HeartMate II® LVAS

LEFT VENTRICULAR ASSIST SYSTEM

INSTRUCTIONS FOR USE

THORATEC CORPORATION

Corporate Headquarters
Thoratec Corporation
6035 Stoneridge Drive
Pleasanton, CA 94588
USA
Business:
Tel.: 925-847-8600
Fax: 925-847-8574
Emergencies:
800-456-1477 (USA HeartLine™)
925-847-8600 (International)
www.thoratec.com

Authorized EU Representative
Thoratec Europe Limited
Burnett House, Lakeview Court
Ermine Business Park
Huntingdon, Cambs PE29 6UA UK
Business:
Tel.: +44(0) 1480 455200
Fax: +44(0) 1480 454126
Urgent/24-Hour:
+44(0) 7659 877901

Emergency HeartLine™ USA: (800)456-1477
Emergencies Outside USA: (925)847-8600
Urgent/24-Hour Europe: +44(0) 7659 877901

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GENERAL INFORMATION

1.0 Introduction

The HeartMate II Left Ventricular Assist System (LVAS) is an axial-flow, rotary ventricular assist system and can generate flows up to 10 liters per minute (lpm). Attached to the apex of the left ventricle and the ascending aorta, the HeartMate II blood pump diverts blood from the weakened left ventricle and propels it to the rest of the body. The System Controller, via its internal computer program, regulates the pump.

WARNING!
A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using this product. Read this entire booklet and the *HeartMate II LVAS Operating Manual* prior to attempting implantation. Completion of Thoratec Corporation's HeartMate II Surgical Training Program is required prior to use of the HeartMate II Left Ventricular Assist System.

2.0 Indications for Use

The HeartMate II LVAS is intended for use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. The HeartMate II LVAS is also indicated for use in patients with New York Heart Association (NYHA) Class IIIB or IV end-stage left ventricular failure who have received optimal medical therapy for at least 45 of the last 60 days, and who are not candidates for cardiac transplantation. The HeartMate II LVAS is intended for use both inside and outside the hospital, or for transportation of ventricular assist device (VAD) patients via ground ambulance, fixed-wing aircraft, or helicopter.

3.0 Contraindications

The HeartMate II LVAS is contraindicated in patients who cannot tolerate anticoagulation therapy.

4.0 Warnings and Precautions

4.1 WARNINGS

- A thorough understanding of the technical principles, clinical applications, and risks associated with left ventricular support is necessary before using this product. Read this entire *HeartMate II LVAS Instructions for Use* (IFU) and the corresponding HeartMate *II LVAS Operating Manual* (document # 103884) before attempting implantation. Completion of the HeartMate II Surgical Training Program is required prior to use of the HeartMate II Left Ventricular Assist System (LVAS). In addition, it is important to read the
  Instruction for Use (IFUs) for the accessories used to power the HeartMate II LVAS, including the Power Module (PM), Universal Battery Charger (UBC), and HeartMate 12 volt nickel metal hydride (NiMH) or HeartMate 14 volt lithium ion (Li-Ion) batteries. See below and section 13.1 for a list of power accessory IFUs.
- Before using any HeartMate power accessories (Power Module, batteries, Universal Battery Charger), all users (including clinicians, patients, and caregivers) must be trained on their use. Manuals for HeartMate power accessories include:
  - *HeartMate 12 Volt NiMH Battery Instructions for Use (IFU)* (document # 103769)
  - *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770)
  - *HeartMate Universal Battery Charger IFU* (document # 103771)
  - *HeartMate Power Module IFU* (document # 103772)
- The HeartMate Power Module (PM) and Universal Battery Charger (UBC) generates and can radiate radio frequency energy. If not installed and used according to instructions, it may cause harmful interference with other devices in the area. There is no guarantee that interference will not occur in a particular installation/use of the PM and/or UBC. Interference can be determined by unplugging/plugging in the PM and turning off/on the UBC and seeing the affect on devices in the area. If interference is detected while the patient is connected to the PM, attempt to correct it by *FIRST* SWITCHING THE SYSTEM TO BATTERY POWER and then:
  - Re-orienting or moving the affected device(s).
  - Increasing the distance between the PM and/or UBC and the affected device(s).
  - Connecting the affected device(s) to an electrical outlet different from the outlet used to power the PM and/or UBC.
  - Consulting Thoratec's Technical Services Department for advice and assistance.
- Do not use the PM or the UBC in the presence of flammable anesthetic agents (e.g., nitrous oxide), or an explosion may occur.

- Connect the PM (and any peripheral devices) only to properly tested, grounded, and AC outlets dedicated to PM use. Do not use an adapter for ungrounded wall outlets or multiple portable socket outlets (power strips), or you may receive a serious electric shock or the pump may stop.
- Do not connect the PM or the UBC to an outlet controlled by a wall switch or the device may be left inoperable.
- The PM, like any piece of electrically-powered life-sustaining equipment should remain continually plugged into a properly-grounded (3 prong) AC mains electrical outlet that is dedicated to its use, except during transport or service/maintenance. The PM's internal battery (that provides limited backup power to the LVAD in the event of AC mains power failure) remains charged as long as the PM is connected to AC power and turned "on." See the *HeartMate II LVAS Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on using the PM.
- The PM contains an internal battery. When new it provides approximately 30 minutes of emergency backup power to the HeartMate II LVAS in the event of AC mains interruption/ failure. If the PM is used in cold conditions (32-59°F, 0-19°C), the backup battery runtime may be reduced to a minimum of 20 minutes.
- The PM is shipped with its internal battery disconnected. It must be connected prior to initial use. If the internal battery is not connected, the backup power source will not work. Make sure the internal battery is connected prior to initial use and after any time the PM is shipped for service or maintenance. See the *HeartMate Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on the PM's internal battery.
- Users should transfer from the PM to batteries during AC mains power failure. The PM will switch to internal back up battery during power interruption/failure. In addition, the PM's battery charge status indicators will not work during AC mains power failure. See the *HeartMate Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on using the PM, including how to transfer to battery-powered operation.
- Keep the PM and the UBC away from water. If the PM has contact with water, shower spray, rain/snow, or wet surfaces, the LVAD may stop or the patient may receive a serious electrical shock. If the UBC has contact with water, shower spray, rain/snow, or wet surfaces, it may prevent the UBC from charging batteries or the patient may receive a serious electrical shock.
- Do not use the HeartMate II LVAS in pregnant women or any woman likely to become pregnant during her period of LVAS support. A growing fetus may dislodge the pump, which may result in device failure or fatal hemorrhage. Anticoagulation regimens are contraindicated during pregnancy.

- Do not subject patients implanted with the HeartMate II LVAS to Magnetic Resonance Imaging (MRI) as the LVAD contains ferro-magnetic components, and MRI could cause device failure or patient injury.
- There may be risks associated with performing external chest compression, in the event of cardiac arrest, due to the location of the outflow graft conduit and the presence of ventricular apical anastomosis. Performing external chest compression may result in damage to the outflow graft conduit or the dislodgement of the LVAD inflow tract.
- Cardiac massage should only be performed by a skilled surgeon, under direct vision in patients who have had recent (i.e., prior to mediastinal healing) device implantation.
- Do not apply high power electrical treatment (e.g., application of diathermy) directly to patient. Application of high power electrical treatments could result in electrical interference with system operation, causing the pump to stop.
- Implanted components should not be exposed to therapeutic levels of ultrasound energy (e.g., ultrasound heating and/or extracorporeal shockwave lithotripsy) used to alter or ablate tissue (this does not apply to diagnostic techniques such as echocardiography), as the device may inadvertently concentrate the ultrasound field and cause harm.
- Therapeutic ionizing radiation may damage the device and the damage may not be immediately detectable.
- Avoid strong static discharges (e.g., television or computer monitor screens) as these can damage the electrical parts of the system and cause the LVAD to stop.
- To prevent device damage and personal injury, refer any servicing of LVAS equipment to authorized Thoratec trained service personnel only.

4.1.1 WARNINGS - Specific Implantation Issues

- Patients with mitral or aortic mechanical valves may be at added risk of accumulating thrombi on the valve when supported with left ventricular assist devices.
- Moderate to severe aortic insufficiency must be corrected at time of device implant.
- Limited clinical data is available supporting safety and effectiveness of the HeartMate II LVAS in patients with a body surface area (BSA) less than $1.5m^2$. The clinical decision to implant the HeartMate II in patients with a BSA less than $1.5m^2$ should be based on individualized assessment of body habitus and device fit.
- Although a small number of pediatric patients (< 21 years) were enrolled in the HeartMate II study, the safety and efficacy of the device in pediatric patients has not been established.

- The clinical trial experience indicates that certain models of implantable cardiac defibrillators (ICDs) and certain implantable pacemakers (IPMs) may, in some cases, not be able to establish telemetry or permit communication between the programmer and the implanted device due to electromagnetic interference when used with the HeartMate II. In such cases the ICDs or IPMs have continued to function properly and only their ability to communicate with the programmer was affected. Specific information on reported cases can be obtained on Thoratec's website at www.thoratec.com. No such difficulties have been reported, other than those observed with device(s) listed on the website.
- Prior to implanting an ICD or IPM in a HeartMate II patient, the device to be implanted should be placed in close proximity to the pump (approximately 10cm) and the telemetry verified. If a patient receives a HeartMate II and has a previously implanted device that is found to be susceptible to this programming interference, Thoratec Corporation recommends replacing the ICD device with one that is not prone to programming interference.
- Do not implant the HeartMate II LVAD if it has been dropped.
- Never operate the HeartMate II Left Ventricular Assist Device (LVAD) in air, as this will immediately damage the device. Liquid must always be present to lubricate the bearings.
- During the implant process, a complete backup system (LVAD implant kit and external components) must be available on-site and in close proximity for use in an emergency.
- All materials and/or components associated with any other surgical procedures must be either removed or adequately secured so as not to interfere with the operation of the HeartMate II LVAS.
- Prior to advancing the inflow conduit into the left ventricle through the apical sewing ring, remove the glove tip from the inflow conduit and the centering tool from the sewing ring. Inspect the ventricle and remove any previously formed clots and trabeculae that may impede flow, or an embolic event or pump stoppage may occur.
- Ensure that the thread protectors have been removed from the outflow elbow and graft prior to attempting connection, or connection will not be possible.
- All entrapped air must be removed from the left heart, blood pump, and conduits in order to minimize the risk of air embolus.
- HeartMate II LVAD is capable of producing negative pressure when the LVAD output exceeds blood flow from the left ventricle. Maintain left atrial pressure at a value greater than 10 mm Hg at all times to prevent air entrainment.
- Initial weaning of cardiopulmonary bypass should ensure a minimum of two liters per minute (lpm) of blood flow to the LVAD in order to prevent air embolism.

Prolonged de-airation may be due to inadequate blood supply to the LVAD or inadequate pre-clotting of the inflow conduit or outflow graft.

- Do not autoclave the pump. Doing so will cause damage to the pump and percutaneous lead.
- A minimum of two fully charged batteries and a pair of compatible battery clips and power leads are required at the time of implant in order to power the system when transporting the patient out of the operating room.
- PMs are shipped to customers with the internal battery disconnected. After receiving the PM, the hospital's biomedical technician or other authorized and trained personnel must open the PM and connect its internal battery prior to using the device. See Section 2.1 of the *HeartMate Power Module IFU* (document #103772).
- Use only the HeartMate UBC to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries. The UBC will charge and test up to four batteries in four hours or less, depending on the initial charge status of the charging batteries. See the *HeartMate Universal Battery Charger IFU* (document #103771) for detailed warnings, precautions, and instructions on using the UBC for charging HeartMate batteries.

4.1.2 WARNINGS - Patient/System Management Issues

- System components must never be immersed. Showers and washing are permitted when the physician approves wound site readiness. During showers, the HeartMate shower kit must be employed.
- In the event that the LVAD stops operating, attempt to restore pump function immediately. In the event that the LVAD stops operating and blood is stagnant in the pump for more than a few minutes (depending on the coagulation status of the patient), there is a risk of stroke or thromboembolism should the device be restarted. There is also the potential for retrograde flow within the LVAD. See *Other Patient Considerations*, in section 15.10, for more information.
- **Disconnecting both System Controller power leads at the same time will cause the pump to stop.** At least one System Controller lead must be connected to a power source (PM, batteries, or EPP) at all times to maintain support. The following will cause the LVAD to stop and blood pumping to cease:
  - Disconnecting both power leads from the PM when operating on PM power.
  - Removing both batteries at the same time from their respective battery clips when operating on batteries.
  - Completely depleting the battery charge when operating on batteries.

- **Disconnecting the percutaneous lead from the System Controller will result in loss of pump function.** The System Controller must be reconnected as quickly as possible to resume pump function.
    - For pump speeds < 8,000 rpm (typical of device implantation), reconnect the System Controller and then press the alarm silence and/or pump start button as quickly as possible to resume pump function.
    - For pump speeds ≥ 8,000 rpm (typical of clinical use), reconnect the System Controller as quickly as possible to resume pump function. Power will automatically be supplied to the pump.
- There is a risk of embolism at device explant or reoperation if manipulation of the pump or conduits is performed prior to initiation of cardiopulmonary bypass and stoppage of LVAD pumping.
- Use of equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may affect the electromagnetic compatibility of the HeartMate II with other devices, resulting in potential interference between the HeartMate II LVAS and other devices.
- The HeartMate II LVAS should not be used adjacent to other equipment or in a stacked configuration with other equipment. The normal operation of the HeartMate II LVAS must be verified when used in these configurations.

4.2 PRECAUTIONS

- **The *HeartMate II LVAS Instructions for Use*, which addresses LVAD preparation and implantation issues, must be used in conjunction with the *HeartMate II LVAS Operating Manual*, which addresses postoperative and patient management issues. These manuals are not intended to replace comprehensive laboratory or educational programs or to supersede appropriate medical judgment.**
- Components of the HeartMate II LVAS that are supplied sterile are intended for single use only and should not be re-used or re-sterilized. Do not use sterile components if sterile packaging is compromised. Contact Thoratec customer service for Return Materials Authorization (RMA).
- Use only the Thoratec supplied UBC to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries. See the *HeartMate Universal Battery Charger IFU* (document # 103771) for detailed warnings, precautions, and instructions on using the UBC to charge HeartMate batteries.
- Make sure the UBC is plugged in and turned on ("I") before placing batteries into charging pockets.
- The UBC cannot test or charge the black sealed lead acid (SLA) HeartMate batteries originally used with the HeartMate Power Base Unit (PBU) (catalog # 26439).
- Keep the UBC away from water or moisture. If the UBC has contact with water/moisture, shower spray, rain/snow, or wet surfaces, the user may receive a serious electric shock or the UBC may fail to operate properly.
- After approximately 70 uses, HeartMate batteries may need to be calibrated. The UBC alerts users when an inserted battery needs to be calibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time. Calibrate a battery as soon as possible after being prompted to do so to prevent a backlog of uncalibrated batteries. See the *HeartMate Universal Battery Charger IFU* (document # 103771) for detailed warnings, precautions, and instructions on using the UBC to calibrate HeartMate batteries.

- Leave a calibrating battery in the UBC for the entire calibration cycle. Removing a battery before it is fully calibrated may result in a fully-depleted battery (the on-battery fuel gauge will reflect this).
- For optimal battery performance, leave charged batteries in their charging pockets until ready for use. Leaving charged batteries in the UBC will not damage them.
- **HeartMate 14 volt Li-Ion batteries must be charged at least once by the end of the month marked on the label placed on battery packaging (box and protective bag)**. If a battery is not charged by this date, battery operating time may be affected, which can cause the pump to stop unexpectedly. Do not use a battery if it has not been charged within the first year of receipt. Discard expired or defective batteries according to local, state, and federal regulations. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) and the *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770).
- HeartMate 12 volt NiMH batteries are compatible with both the HeartMate XVE and HeartMate II LVAS and can power both systems. HeartMate 14 volt Li-Ion batteries are for use exclusively with the HeartMate II LVAS. HeartMate 14 volt Li-Ion batteries are NOT compatible with the XVE system and cannot provide power to the XVE LVAS. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) and the *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770) for detailed warnings, precautions, and instructions on using HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries to power the HeartMate II LVAS. See ***Batteries are** the same color as their corresponding battery clips.
- Table 17 for distinguishing characteristics of HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries.
- HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries are compatible only with corresponding battery clips. Use 12 volt NiMH batteries with 12 volt battery clips and 14 volt Li-Ion batteries with 14 volt battery clips. Incompatible clips cannot transfer power to the LVAS. Ensure you are using compatible batteries and battery clips before relying on them for power. Using incompatible batteries/battery clips will result in pump failure.
- Do not use batteries below 32°F (0°C) or above 104°F (40°C) or they may fail suddenly. If batteries are below room temperature (68–72°F, 20–23°C) during use, their capacity will be reduced. At the low end of the temperature range (32°F, 0°C), run time will be reduced by 50%. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) and the *HeartMate 14 Volt Li-Ion IFU* (document # 103770) for recommended storage guidelines.
- If stored and used within recommended guidelines, HeartMate batteries should be usable for approximately 360 use/charge cycles *or* for 36 months from the date of manufacture, whichever comes first. After 360 cycles/36 months, battery performance cannot be guaranteed and batteries should be replaced. See the

HeartMate 12 Volt NiMH Battery IFU (document # 103769) and the *HeartMate 14 Volt Li-Ion IFU* (document # 103770).

- Use of expired or defective batteries may result in reduced operating time or an abrupt loss of HeartMate II LVAD function.
- As batteries get older, they will support the system for shorter periods of time. If a pair of batteries does not give at least four hours of support, remove both batteries from service.
- To prevent deterioration or damage to batteries:
  - Do NOT drop batteries or hit them against hard objects or each other.
  - Do NOT use batteries in temperatures that are below 32°F (0°C) or above 104°F (40°C).
  - Do NOT leave or store batteries in extremely hot or cold temperatures (e.g., in cars or car trunks), or battery life will be shortened.
  - Do NOT directly connect battery contacts to each other.
  - Do NOT immerse batteries in water or liquid.
- Do not store batteries together with keys, coins, or other loose metallic objects. Metal objects touching the exposed battery contacts may cause an accidental short or connection between battery contacts, which can result in battery overheating that may burn the user or damage the batteries.
- The HeartMate Emergency Power Pack (EPP) is an emergency power source that can power the HeartMate II LVAS for up to 12 hours in the event of AC main power interruption or failure. The EPP is for emergency use only and is not intended as a routine power source. It is not rechargeable and must be replaced if used for a period exceeding three hours. The EPP is mandatory for HeartMate II patients. See the *HeartMate II LVAS Operating Manual* (document # 103884) for detailed warnings, precautions, and instructions on using the EPP.
- Do not store or use the EPP below 32°F (0°C) or above 122°F (50C), or it may fail suddenly. If the EPP is below room temperature (68–72°F, 20–23°C) during use, it will run the pump for less than 12 hours. At the low end of the temperature range (32°F, 0°C), run time will be reduced by 50%.
- To prevent deterioration or damage to the EPP:
  - Do not leave or store the EPP in hot or cold areas (car trunk, etc.) or battery life will be shortened.
  - Do not use the EPP beyond the expiration date.
- Dispose of expired, used, or damaged batteries and EPPs according to local, state, or federal regulations. Do not incinerate.

- Avoid unnecessary pulling or movement of the external portion of the percutaneous lead, especially as the skin exit site is healing. Pulling or movement could prolong the healing process or disrupt an already healed exit site. Disruption of the percutaneous lead exit site increases the patient's risk of acquiring a serious infection.
- Connectors should be kept clean and dry. Do not expose connectors to water/moisture or dirt when making or breaking connections.
- Never use tools to tighten connections. Hand-tighten only. Using tools may damage the connectors and cause the pump to stop.
- The use of other electronic devices (medical or non-medical) that do not comply with the equivalent safety requirements of the PM may lead to reduced patient safety. When considering whether or not to use an electronic device on or near the patient, use only those devices necessary for patient safety and well-being.
- Avoid discharging static electricity to the System Controller or LVAD percutaneous lead.
- Pump flow readings will vary with changes in blood viscosity.
- If external defibrillation becomes necessary, do NOT disconnect the System Controller from the percutaneous lead prior to delivering the shock.
- If open chest defibrillation is required, it is advised that the HeartMate II LVAS be disconnected prior to delivering the shock.
- Ensure that all backup System Controllers are programmed with identical settings (e.g., fixed speed setting and low speed limit) as the primary controller. Controllers are shipped with factory settings, and therefore backup controllers must be programmed at the time they are assigned to a patient.

4.2.1 PRECAUTIONS - Specific Implantation Issues

- Care must be taken to prevent blood from entering and collecting in the lumen of the conduits. Blood on the inner lumen may increase the risk of thromboembolism due to coagulum breaking free in the circulatory system. The inner lumen must therefore be rinsed thoroughly prior to attachment to the LVAD.
- Do not use pre-clotting agents that require heat on the inflow conduit, as the inflow conduit cannot be autoclaved.
- Do not over tighten thread protectors.
- Do not allow the apical coring knife to involve the ventricular septum while performing the left ventricle coring.

- Do not remove the centering fixture inside the apical sewing ring until ready to insert the inflow conduit.
- Do not clamp the bend relief segment of the outflow graft.
- The outflow graft must not be kinked or positioned where it could abrade against a pump component or body structure.
- Do not clamp the flexible silicone segment of the inflow conduit.
- All entrapped air must be removed from the LVAD blood path prior to fully releasing the outflow graft cross-clamp.
- Once the LVAD is activated, reduce cardiopulmonary bypass flow rapidly to provide ample blood flow to the LVAD. Whenever possible, maintain the HeartMate II at a pump flow greater than 3 lpm and a pump speed greater than 8,000 rpm.
- Remove all vents on the inflow side of the LVAD, including needles in the pulmonary vein, left atrium, and left ventricle prior to initiation of pumping.
- Prolonged de-airing may be due to inadequate blood volume in the pump. Initial weaning off cardiopulmonary bypass should provide a minimum of two lpm of blood flow through the ventricle and blood pump in order to eliminate the possibility of entraining air.

4.2.2 PRECAUTIONS - Patient/System Management Issues

- Diligent care throughout the course of support must be exercised to prevent infection and sepsis. Systemic infections and localized infection of the percutaneous lead exit site may occur with use of this device. Infection may contribute to patient morbidity and death.
- The use of automated blood pressure monitoring devices may not yield accurate blood pressure data. Manual auscultation to assess blood pressure is recommended. In circumstances where the flow is pulseless, invasive blood pressure monitoring or the use of Doppler ultrasound may be required.
- Pump flow is estimated from the pump power, and under abnormal conditions may result in an overestimation or not display a reading. No single parameter is a surrogate for monitoring the clinical status of the patient and the changes in all parameters should be considered when assessing a situation.
- Right heart failure can occur following implantation of the device. Right ventricular dysfunction, especially when combined with elevated pulmonary vascular resistance, may limit LVAS effectiveness due to reduced filling of the LVAD.
- An electrocardiogram may be indicated to rule out fibrillation if a patient complains of feeling "different" (e.g., heart racing, short of breath, heart pains).
- Reports of change in sounds and/or motion of the system by the patient should prompt evaluation for cause, including the possibility of device malfunction. Sounds that could signal an issue include grinding or intermittent "whirring."
- Physiological factors that affect the filling of the pump, such as hypovolemia or postural hypotension, will result in reduced pump flows as long as the condition persists. Pump flows will not be restored to normal unless such conditions are treated.
- The externalized portion and the lumen of the percutaneous lead at explant are not sterile, and care must be taken to avoid contamination of the sterile field. Sterile glove fingertips can be attached to the ends of the lead once cut to minimize the risk of contact with the sterile field.
- When connecting leads, do not force the connectors together without proper alignment. Forcing together misaligned connectors may damage them.
- A backup System Controller, spare batteries, and a pair of compatible battery clips must be with the patient at all times for use in an emergency.
- A patient's primary source of power during mobile operation (i.e., while not connected to AC mains electrical power) should be the HeartMate batteries. The use of DC power from a car's power adapter should be temporary and for convenience only. DC power can vary from vehicle to vehicle. If a car's DC power is inadequate to power the LVAS, the PM will alarm or switch to back-up battery power. If this

occurs, switch to portable battery power and discontinue the use of DC input power to the PM.

- The use of DC power from an automobile power outlet is intended for convenience while traveling by car. DC power from an automobile power outlet is NOT meant to be a primary power source; its use should be temporary only. While traveling by car and using DC power, the patient should have at least one set of charged HeartMate batteries and cables in close proximity. See Section 8.0, "Traveling by Car," in the *HeartMate Power Module IFU* (document #103772) for detailed warnings, precautions, and instructions on using automobile DC power
- The automobile engine must be ON and RUNNING BEFORE connecting the PM to its DC power outlet.
- The PM requires planned maintenance at least once every 12 months for the best possible operation. Planned maintenance includes (but need not be limited to): a checking, cleaning, and inspecting all internal connections, replacing the internal battery (the internal battery is rechargeable, but has a limited life), and replacing the PM patient cable.
- PM service and maintenance should be performed only by service personnel who are trained and authorized by Thoratec Corporation.
- Do not clean or service the PM while it is providing power to the system.
- If the System Monitor is mounted on top of the PM, do NOT attempt to lift or carry the two devices together by using the System Monitor handle. Doing so may damage the PM and/or System Monitor.
- PM connectors should be kept clean and dry. Do not expose Power Module connectors to water, moisture, rain/snow, dirt, etc.
- When connecting PM connectors, do not force together connectors without proper alignment. Forcing together misaligned connectors may damage them.
- Use only the HeartMate Universal Battery Charger (UBC) to charge HeartMate 12 volt NiMH and 14 volt Li-Ion batteries. Other battery chargers may damage HeartMate batteries.
- The UBC requires planned maintenance at least once every 12 months for the best possible operation. Planned maintenance includes (but need not be limited to): a functional check of the device and cleaning/inspecting all internal connections.
- Service and maintenance of the HeartMate UBC should be performed only by service personnel who are trained and authorized by Thoratec Corporation.
- Make sure the UBC is plugged in and turned on ("I") before placing batteries into the pockets for charging.

- After approximately 70 uses, HeartMate batteries may need to be recalibrated. The UBC indicates when a battery needs to be recalibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time. Calibrate a battery as soon as possible after being prompted to prevent a backlog of uncalibrated batteries. See Section 4.0, "Calibrating HeartMate Batteries," in the *HeartMate Universal Battery Charger IFU* (document #103771).
- Leave a calibrating battery in the UBC for the full calibration cycle. Removing a battery before it is fully calibrated may result in a depleted battery (the on-battery fuel gauge will reflect this status). See Section 4.0, "Calibrating HeartMate Batteries," in the *HeartMate Universal Battery Charger IFU* (document #103771).
- The metal contacts inside the UBC pockets should be kept clean and dry. Do not expose contacts to water, moisture, dirt, etc. Do not touch these contacts when the charger is connected to AC mains and turned on ("I").
- Dirty metal contacts inside the battery charging pockets may prevent proper battery charging, which can affect battery operation. The metal contacts inside the pockets should be cleaned at least once a month. TURN OFF and UNPLUG the UBC before cleaning. Do NOT clean the UBC while it is in use.
- Clean dirty metal contacts inside the charging pocket of the UBC with a lint-free cloth or swab that has been moistened (not dripping) with rubbing alcohol. Allow the alcohol to dry before inserting batteries into the pocket(s) for charging.

5.0 Adverse Events

Adverse events that may be associated with the use of the HeartMate II left ventricular assist system (LVAS) are listed below.

- Death
- Bleeding, perioperative or late
- Cardiac arrhythmia
- Local infection
- Respiratory failure
- Device malfunction
- Sepsis
- Right heart failure
- Percutaneous or pocket infection
- Renal failure
- Stroke
- Neurologic dysfunction
- Psychiatric episode
- Thromboembolic event, peripheral
- Hemolysis
- Hepatic dysfunction
- Device thrombosis
- Myocardial infarction

6.0 Summary of Clinical Studies

NOTE:
Thoratec reserves the right to change specifications without notice.

6.1 Bridge to Transplantation Study Overview

One hundred twenty-six (126) patients were enrolled in the HeartMate II (HMII) Bridge-to-Transplantation (BTT) Primary Study Cohort between March 2005 and March 2007 at 26 investigational sites across the United States as the pivotal study sample size. The primary objective of the study was to determine the safety and effectiveness of the HeartMate II LVAS as a BTT device in end-stage heart failure patients who are listed for cardiac transplant and at imminent risk of death. Effectiveness of the device was assessed on the basis of the percentage of patients surviving either to cardiac transplantation or 180 days of LVAS support while being listed UNOS 1A/1B. Safety of the HeartMate II LVAS was assessed by the incidence of adverse events during LVAS support.

A number of secondary objectives were also evaluated during the study, including clinical reliability (malfunctions/failures), functional status (6-minute walk and patient activity score), quality of life (Minnesota Living with Heart Failure and Kansas City Cardiomyopathy Questionnaire), re-operations, neuro-cognitive assessment (memory, language, visual/spatial perception, processing speed and abstract/executive function), and 30-day and 180-day post-transplant survival.

After completion of enrollment in the Primary Study Cohort, enrollment continued under a Continued Access Protocol (CAP), which was identical to the Primary Study Cohort protocol. Patients who were originally enrolled into these two study cohorts but who had a body surface area (BSA) less than $1.5m^2$ were separated out into a Small BSA Patient cohort for analysis.

6.1.1 Study Design

The study was a multi-center, non-blinded, non-randomized, prospective study. The study had two oversight committees, a Clinical Events Committee which adjudicated all adverse events and deaths and a Data and Safety Monitoring Board which reviewed the study data periodically to ensure that continuation of the study did not present any unacceptable risk. The members of these committees were independent of Thoratec, the investigational sites and the principal investigators.

The primary study outcomes were defined as death, cardiac transplantation, device explantation due to myocardial recovery, or survival to 180 days on LVAS support while remaining listed UNOS 1A/1B. After reaching the 180 day assessment point, patients continued to be followed until transplantation, explantation or death.

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6.1.2 Patient Population

The patients enrolled into the HeartMate II study were patients listed for cardiac transplant in end-stage heart failure who demonstrated no evidence of severe end-organ damage that would make HeartMate II LVAS implantation futile. The BTT inclusion and exclusion criteria were based on study criteria used in previously approved LVAD BTT studies. The criteria included patients in New York Heart Association (NYHA) class IV heart failure, on inotropic support, and without contraindication to listing for cardiac transplantation as UNOS Status 1A or 1B. If the patient was 1B, they also needed to meet hemodynamic criteria to qualify, including pulmonary capillary wedge pressure (PCWP) or pulmonary artery diastolic pressure (PAD) > 20 mmHg and either a cardiac index <2.2 L/min/m^2 or systolic blood pressure <90 mmHg. The exclusion criteria excluded patients with moderately severe end-organ damage, as evidenced by elevated total bilirubin, elevated creatinine values, or low platelet counts, and also excluded patients that may not be able to tolerate the management of the HeartMate II LVAS due to intolerance to anticoagulation or compliance issues.

Two hundred and seventy-nine (279) patients were enrolled at 33 study sites between March 2005 and March 2007. Twenty-six (26) sites enrolled patients into both the Primary Study Cohort and the Continued Access Protocol Cohort (CAP). Seven additional sites enrolled patients only under the Continued Access Protocol. Of the 279 patients enrolled into the three cohorts of the HeartMate II study (Primary Study, Continued Access, and Small BSA), 194 patients have been followed to a study outcome point, and if ongoing on HeartMate II LVAS support, for at least one year as of September 14, 2007, and are presented in the following clinical summary. As shown in **Figure 1**, the 194 patients are divided among three cohorts; 126 patients in the Primary Study cohort and 58 patients in the Continued Access Protocol cohort. An additional 10 patients were originally enrolled in these two cohorts but were separated out for analysis in the Small BSA Patient cohort ($1.2m^2 \leq BSA < 1.5m^2$). Data are presented for each cohort separately and also in the aggregate for all 194 patients.

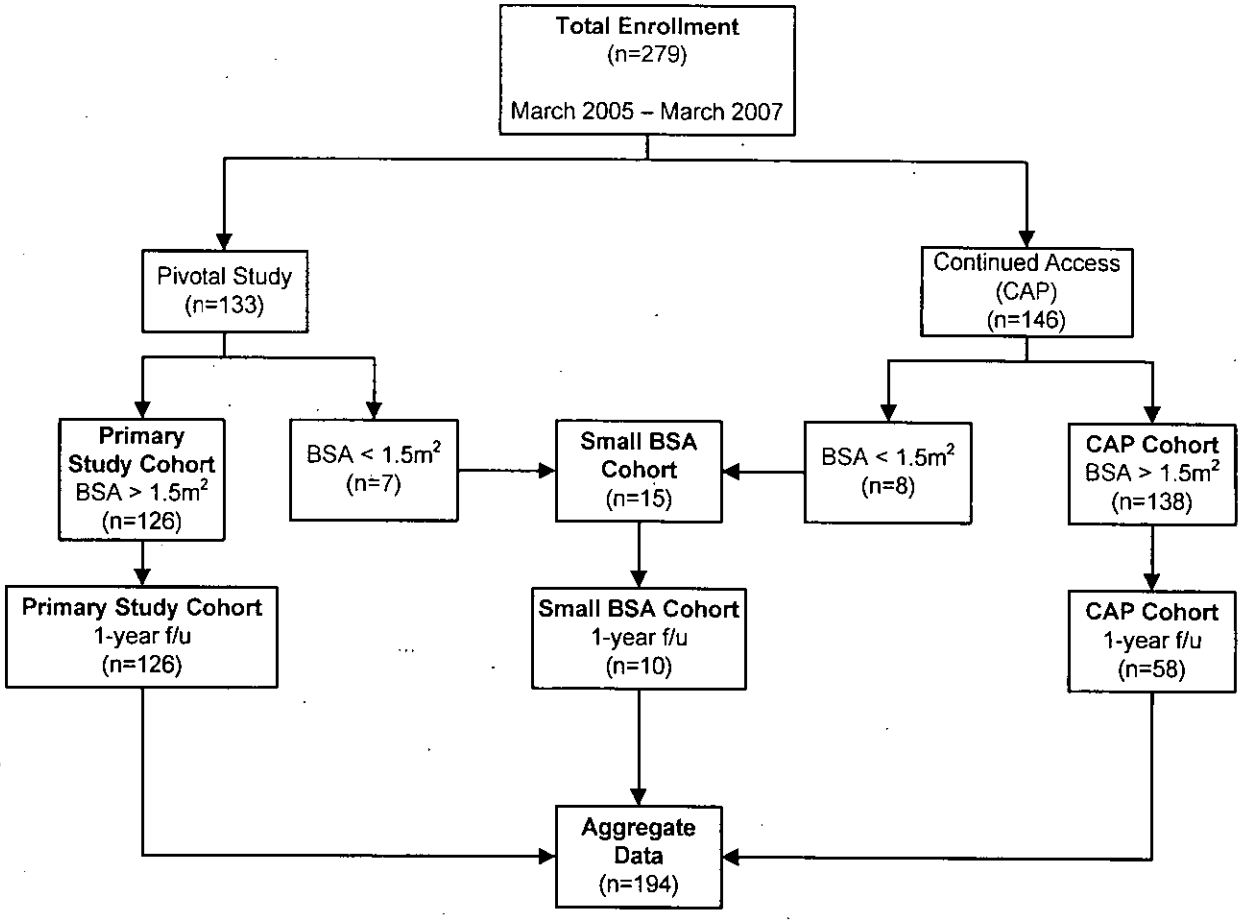


Figure 1 HeartMate II Study Enrollment

The overall mean age in the HeartMate II LVAS study was 51 years (range 16-69 years). The smallest patient implanted had a BSA of 1.33m^2 and the largest patient, a BSA of 2.62m^2, with a mean BSA of 1.99m^2. The mean body mass index (BMI) was 27 kg/m^2 (range 15.6 – 44.0 kg/m^2). The most prevalent etiology was idiopathic cardiomyopathy (48%) followed by ischemic cardiomyopathy (41%). Of note in the cardiovascular history is that 78% of the patients had pre-existing arrhythmias and 76% of the patients entered the study with implantable cardiac defibrillators (ICD). Patient demographics and cardiovascular history for each of the three study cohorts and the aggregate data are shown in **Table 1** and **Table 2**.

	Primary Cohort (n = 126)	CAP Cohort (n= 58)	Small BSA Cohort (n = 10)	Aggregate Data (n = 194)
Age (years)*	55 (17 -68)	56 (16-69)	47 (20 – 69)	55 (16-69.1)
Etiology	39% Ischemic	50% Ischemic	10% Ischemic	41% Ischemic
Gender	83% Male 17% Female	78% Male 22% Female	0% Male 100% Female	77% Male 23% Female
BMI (kg/m^2)*	26.5 (10–40)	27.6 (18-44)	17.0 (15.6-20.8)	26.6 (15.6-44.0)
BSA (m^2)*	1.99 (1.5 – 2.6)	2.00 (1.52 – 2.57)	1.40 (1.33 – 1.47)	1.99 (1.33-2.62)

*Median and range

Table 1 Patient Demographics

	Primary Cohort (n = 126)	CAP Cohort (n = 58)	Small BSA Cohort (n = 10)	Aggregate Data (n = 194)
Arrhythmias	101 (80%)	46 (79%)	5 (50%)	152 (78%)
Ventricular Arrhythmias	71 (56%)	34 (59%)	0 (0%)	109 (56%)
Ventricular Pacing	77 (61%)	35 (60%)	5 (50%)	117 (60%)
Biventricular Pacing	61 (48%)	30 (52%)	0 (0%)	95 (49%)
Implantable Cardioverter / Defibrillator	96 (76%)	45 (78%)	6 (60%)	147 (76%)
Stroke	12 (10%)	6 (10%)	1 (10%)	19 (10%)

Table 2 Cardiovascular History

6.1.3 Primary Objective: Transplant or Survival to 180 Days While Listed on UNOS 1A/1B

Overall Patient Outcomes

After reaching the 180 day assessment point, patients continued to be followed until transplantation, explantation or death. Patient outcomes for each study cohort (Primary, CAP, Small BSA and Aggregate Data) as of September 14, 2007 are presented in **Table 3**.

The pre-specified primary endpoint for the Primary Study Cohort of HeartMate II LVAS BTT pivotal study was "patient survival to cardiac transplantation or 180 days of LVAS support while remaining listed status 1A or 1B." The HeartMate II pivotal study was to be prospectively determined successful if the one-sided 95% lower confidence limit of the true success rate exceeded 65%, the Performance Goal. The results show that the lower confidence limit (LCL) of success was 64.0% in the Primary Study Cohort, thereby not quite meeting the pre-specified agreed-upon LCL endpoint, > 65%. Although outcomes were similar in the CAP and Small BSA cohorts, the LCLs are lower due to the smaller sample sizes. Additional study results are presented in **Table 4**.

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
Cardiac Transplantation[1]	72 (57%)	33 (57%)	7 (70%)	112 (58%)
Myocardial Recovery[1]	4 (3%)	2 (3%)	0 (0%)	6 (3%)
Supported ≥ 180 days and:				
Listed UNOS Status 1A or 1B[1]	13 (10%)	5 (9%)	0 (0%)	18 (9%)
Not listed Status 1A or 1B[2,3]	9 (7%)	7 (12%)	3 (30%)	19 (10%)
Expired < 180 days on LVAD[2]	25 (20%)	11 (19%)	0 (0%)	36 (19%)
Treatment failure; received other VAD[2]	3 (2%)	0 (0%)	0 (0%)	3 (2%)
Pre-specified Lower 95% Confidence Limit of True Success Rate	65.0%			
Observed Lower 95% Confidence Limit of Study Success Rate	64.0%	59.0%	46.2%	64.7%

[1] Classified as success per pre-specified study criteria
[2] Classified as failure per pre-specified study criteria
[3] Reasons for not listing included medical ineligibility, elective withdrawal from transplant list, substance abuse and non-compliance with medical therapy

Table 3 Primary Study Outcomes (as of September 14, 2007)

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
30 day (peri-operative) mortality	12 (10%)	7 (12%)	0 (0%)	19 (10%)
Patient survival to hospital discharge/transplant	105 (83%)	48 (83%)	10 (100%)	163 (84%)
Median time to transplant (days)	102.5	152	194	117
Median duration of device support (days)	117	163.5	374	131.5
Cumulative support duration (patient–years)	71	29	9	109

Table 4 Additional Study Results (as of September 14, 2007)

Plots of the competing outcomes (transplantation, weaning due to myocardial recovery, expiration, ongoing LVAS support and study withdrawal) are provided in **Figure 2** and **Figure 3** for the Primary Study Cohort and the Aggregate Data, respectively.

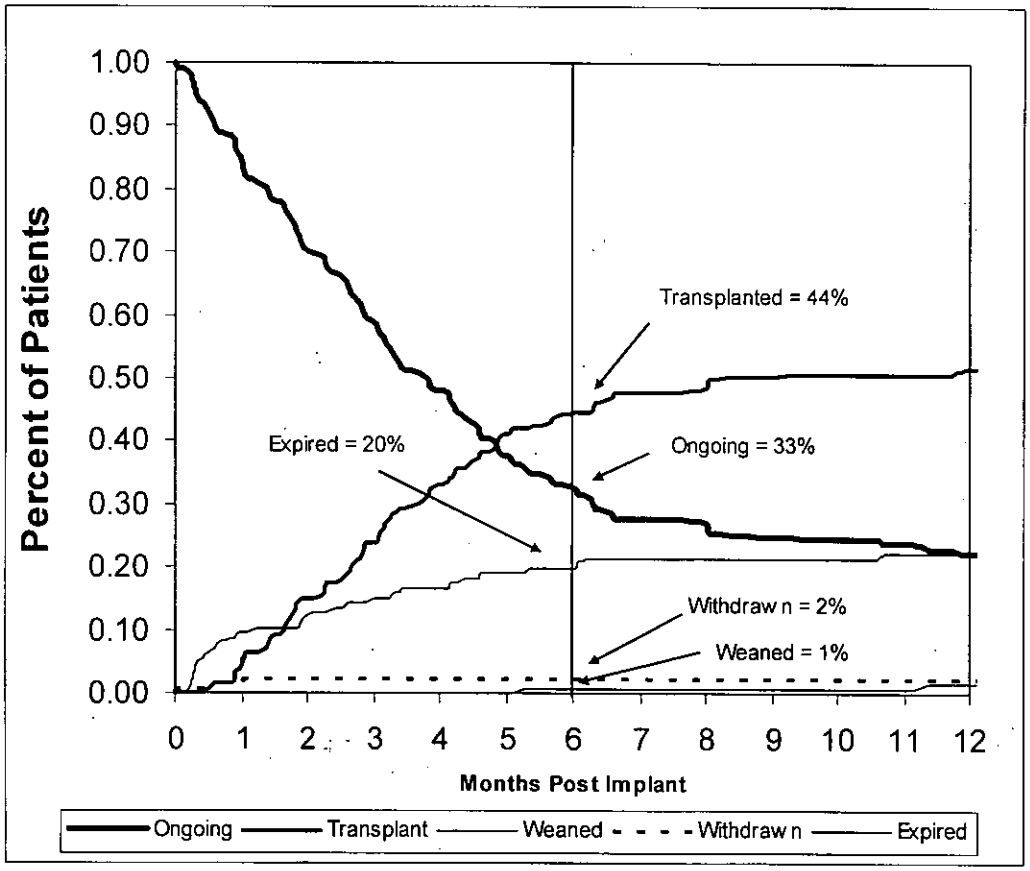


Figure 2 Competing Outcome Plot of HeartMate II Bridge-to-Transplant Primary Study Cohort (n=126) as of September 14, 2007

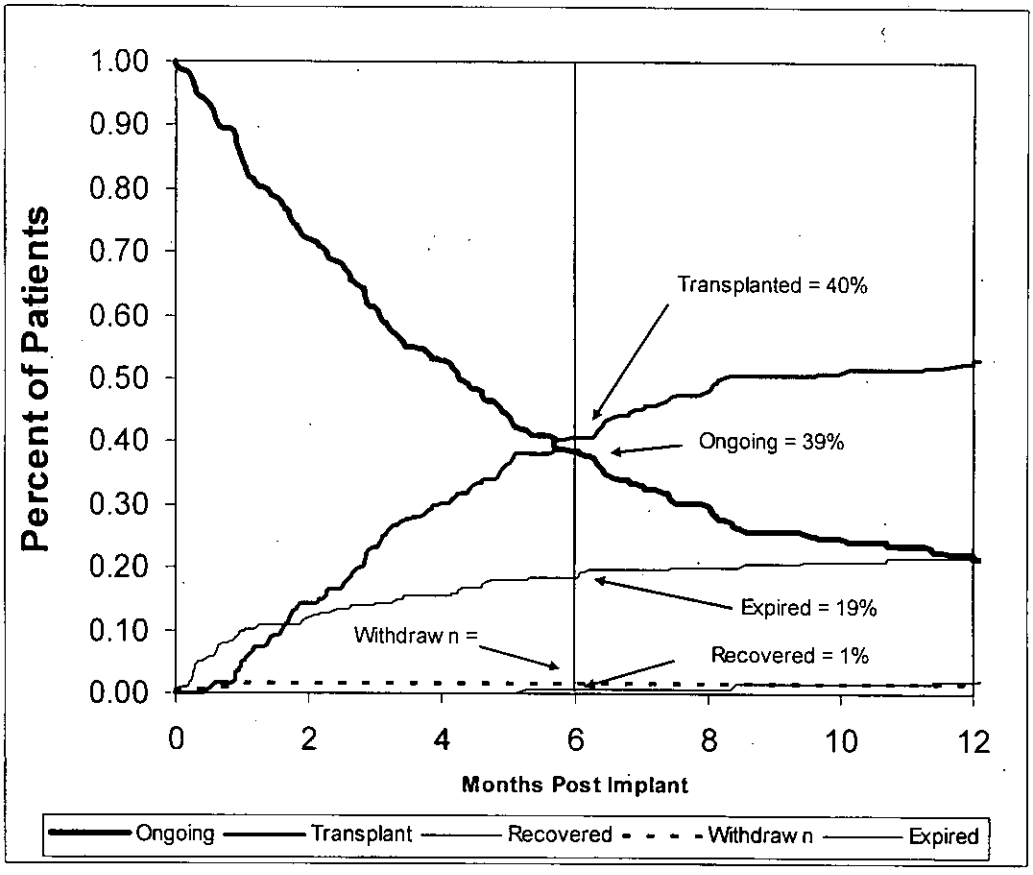


Figure 3 Competing Outcome Plot of HeartMate II Bridge-to-Transplant Aggregate Data (n=194) as of September 14, 2007

Safety: Adverse Events

The incidence of all adverse events observed during the HeartMate II LVAS study, regardless of severity, is provided in **Table 5** for each data cohort. Adverse events were defined as events that occurred while on HeartMate II LVAS support that may have a deleterious effect on the patient. The incidence of adverse events defined as serious are presented in **Table 6**. Adverse Events were classified as serious if they resulted in death or permanent disability, were life threatening, required hospitalization or prolonged hospitalization. Adverse event rates during various time intervals are presented in **Table 7**, which shows that the majority of adverse events occurred during the first 30 days after implantation of the device.

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
	# Pts (% Pts)	# Pts (% Pts)	# Pts (% Pts)	# Pts (% Pts)
Bleeding (all requiring PRBC ≥2)*	89 (71%)	35 (60%)	9 (90%)	133 (69%)
Bleeding requiring surgery	37 (29%)	15 (26%)	4 (40%)	56 (29%)
Stroke	12 (10%)	3 (5%)	2 (20%)	17 (9%)
Peri-operative (≤POD2)	5 (4%)	0 (0%)	0 (0%)	5 (3%)
Post-operative (>POD2)	7 (6%)	3 (5%)	2 (20%)	12 (6%)
Other Neurological**	12 (10%)	3 (5%)	2 (20%)	17 (9%)
Local Infection	36 (29%)	21 (36%)	3 (30%)	60 (31%)
Drive Line Infection	20 (16%)	4 (7%)	2 (20%)	26 (13%)
Pocket Infection	2 (2%)	2 (3%)	0 (0%)	4 (2%)
Sepsis	27 (21%)	7 (12%)	2 (20%)	36 (19%)
Right Heart Failure	22 (17%)	11 (19%)	3 (30%)	36 (19%)
Peripheral TE	10 (8%)	1 (2%)	0 (0%)	11 (6%)
Respiratory Failure	33 (26%)	17 (29%)	3 (30%)	53 (27%)
Cardiac Arrhythmias	77 (61%)	28 (48%)	6 (60%)	111 (57%)
Renal Failure	17 (13%)	6 (10%)	2 (20%)	25 (13%)
Hepatic Dysfunction	3 (2%)	0 (0%)	0 (0%)	3 (2%)
Device Thrombosis	2 (2%)	1 (2%)	0 (0%)	3 (2%)
Hemolysis	3 (2%)	2 (3%)	3 (30%)	8 (4%)
Psychological	8 (6%)	3 (5%)	2 (20%)	13 (7%)
Myocardial Infarction	1 (1%)	(0%)	1 (10%)	2 (1%)
Confirmed Malfunctions	36 (29%)	11 (19%)	6 (60%)	53 (27%)

*Bleeding requiring PRBC ≥ 2 units or surgery.
**Includes transient ischemic attacks (TIA) and non-stroke neurological events.

Table 5 All Adverse Events as of September 14, 2007

	Primary Cohort (n=126)	CAP Cohort (n=58)	Small BSA Cohort (n=10)	Aggregate Data (n=194)
	# Pts (% Pts)	# Pts (% Pts)	# Pts (% Pts)	# Pts (% Pts)
Bleeding (all requiring PRBC ≥2)*	75 (60%)	34 (59%)	8 (80%)	117 (60%)
Bleeding requiring surgery	38 (30%)	15 (26%)	4 (40%)	56 (29%)
Stroke	12 (10%)	3 (5%)	2 (20%)	17 (9%)
Peri-operative (≤POD2)	5 (4%)	0 (0%)	0 (0%)	5 (3%)
Post-operative (>POD2)	7 (6%)	3 (5%)	2 (20%)	12 (6%)
Other Neurological**	11 (9%)	3 (5%)	1 (10%)	15 (8%)
Local Infection	27 (21%)	16 (28%)	2 (20%)	45 (23%)
Drive Line Infection	12 (10%)	3 (5%)	1 (10%)	16 (8%)
Pocket Infection	2 (2%)	2 (3%)	0 (0%)	4 (2%)
Sepsis	26 (21%)	7 (12%)	2 (20%)	35 (18%)
Right Heart Failure	22 (17%)	11 (19%)	3 (30%)	36 (19%)
Peripheral TE	9 (7%)	1 (2%)	0 (0%)	10 (5%)
Respiratory Failure	33 (26%)	17 (29%)	3 (30%)	53 (27%)
Cardiac Arrhythmias	56 (44%)	21 (36%)	5 (50%)	82 (42%)
Renal Failure	17 (13%)	6 (10%)	2 (20%)	25 (13%)
Hepatic Dysfunction	3 (2%)	0 (0%)	0 (0%)	3 (2%)
Device Thrombosis	2 (2%)	1 (2%)	0 (0%)	3 (2%)
Hemolysis	3 (2%)	2 (3%)	1 (10%)	6 (3%)
Psychological	2 (2%)	1 (2%)	0 (0%)	3 (2%)
Myocardial Infarction	1 (1%)	0 (0%)	1 (10%)	2 (1%)
Confirmed Malfunctions	10 (8%)	4 (7%)	3 (30%)	17 (9%)

*Bleeding requiring PRBC ≥ 2 units or surgery.
**Includes transient ischemic attacks (TIA) and non-stroke neurological events.

Table 6 Serious Adverse Events as of September 14, 2007

Adverse Events	Cohort	0 – 7 days	8 – 30 days	31 – 90 days	91 – 180 days	> 180 days
Bleeding	Primary (n=126)	36.25	5.25	1.60	0.58	0.60
	CAP (n=58)	30.91	4.41	1.45	0.91	0.39
	Small BSA (n=10)	60.00	4.84	2.00	2.48	0.96
	Aggregate (n=194)	3.53	4.99	1.59	0.85	0.60
Stroke	Primary (n=126)	2.08	0.28	0.00	0.22	0.09
	CAP (n=58)	0.00	0.29	0.14	0.26	0.00
	Small BSA (n=10)	0.00	0.00	1.33	0.00	0.00
	Aggregate (n=194)	1.36	0.27	0.13	0.21	0.06
Other Neurological	Primary (n=126)	0.42	0.41	0.27	0.15	0.09
	CAP (n=58)	0.91	0.29	0.14	0.00	0.00
	Small BSA (n=10)	0.00	1.61	0.67	0.99	0.00
	Aggregate (n=194)	0.54	0.45	0.26	0.17	0.06
Local Infection	Primary (n=126)	8.33	2.62	1.67	0.36	0.18
	CAP (n=58)	10.00	2.65	1.45	0.39	0.00
	Small BSA (n=10)	0.00	1.61	0.67	0.50	1.34
	Aggregate (n=194)	8.42	2.58	1.55	0.38	0.27
Drive Line Infection	Primary (n=126)	0.00	0.00	0.27	0.58	0.48
	CAP (n=58)	0.00	0.00	0.29	0.26	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.99	0.38
	Aggregate (n=194)	0.00	0.00	0.26	0.51	0.37
Pocket Infection	Primary (n=126)	0.00	0.14	0.00	0.00	0.03
	CAP (n=58)	0.00	0.00	0.00	0.13	0.10
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00
	Aggregate (n=194)	0.00	0.09	0.00	0.04	0.04
Sepsis	Primary (n=126)	1.67	1.80	0.47	0.36	0.24
	CAP (n=58)	1.82	0.59	0.00	0.26	0.10
	Small BSA (n=10)	0.00	1.61	0.00	0.00	0.57
	Aggregate (n=194)	1.63	1.42	0.30	0.30	0.25
Right Heart Failure	Primary (n=126)	1.67	1.80	0.33	0.00	0.03
	CAP (n=58)	3.64	2.06	0.00	0.00	0.00
	Small BSA (n=10)	5.00	1.61	0.00	0.00	0.19
	Aggregate (n=194)	2.45	1.87	0.21	0.00	0.04

Continued on following page.

Table 7 Adverse Event Rate per Patient Year by Time Interval

Table 7 (continued)

Adverse Events	Cohort	0 – 7 days	8 – 30 days	31 – 90 days	91 – 180 days	> 180 days
Peripheral TE	Primary (n=126)	1.25	0.83	0.13	0.00	0.00
	CAP (n=58)	0.91	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00
	Aggregate (n=194)	1.09	0.53	0.09	0.00	0.00
Respiratory Failure	Primary (n=126)	7.92	1.66	0.47	0.22	0.03
	CAP (n=58)	10.91	1.76	0.14	0.26	0.00
	Small BSA (n=10)	10.00	1.61	0.67	0.00	0.00
	Aggregate (n=194)	8.97	1.69	0.39	0.21	0.02
Cardiac Arrhythmias	Primary (n=126)	25.00	4.01	1.47	1.09	0.48
	CAP (n=58)	14.55	5.59	0.72	0.52	0.39
	Small BSA (n=10)	20.00	4.84	0.67	1.49	0.57
	Aggregate (n=194)	21.74	4.54	1.20	0.94	0.47
Renal Failure	Primary (n=126)	3.75	0.69	0.13	0.15	0.00
	CAP (n=58)	2.73	0.59	0.00	0.13	0.00
	Small BSA (n=10)	10.00	0.00	0.00	0.00	0.00
	Aggregate (n=194)	3.80	0.62	0.09	0.13	0.00
Hepatic Dysfunction	Primary (n=126)	0.42	0.14	0.07	0.00	0.00
	CAP (n=58)	0.00	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00
	Aggregate (n=194)	0.27	0.09	0.04	0.00	0.00
Device Thrombosis	Primary (n=126)	0.42	0.00	0.07	0.00	0.00
	CAP (n=58)	0.91	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.00	0.00
	Aggregate (n=194)	0.54	0.00	0.04	0.00	0.00
Hemolysis	Primary (n=126)	0.83	0.00	0.00	0.00	0.03
	CAP (n=58)	0.00	0.00	0.00	0.13	0.10
	Small BSA (n=10)	10.00	0.00	0.00	0.50	0.00
	Aggregate (n=194)	1.09	0.00	0.00	0.09	0.04
Psychological	Primary (n=126)	1.67	0.14	0.07	0.29	0.00
	CAP (n=58)	1.82	0.29	0.00	0.00	0.00
	Small BSA (n=10)	5.00	1.61	0.00	0.00	0.00
	Aggregate (n=194)	1.90	0.27	0.04	0.17	0.00

Continued on following page

Table 7 (continued)

Adverse Events	Cohort	0 – 7 days	8 – 30 days	31 – 90 days	91 – 180 days	> 180 days
Myocardial Infarction	Primary (n=126)	0.00	0.00	0.07	0.00	0.00
	CAP (n=58)	0.00	0.00	0.00	0.00	0.00
	Small BSA (n=10)	0.00	0.00	0.00	0.50	0.00
	Aggregate (n=194)	0.00	0.00	0.04	0.04	0.00

No new adverse events were observed in the HeartMate II LVAS study that have not been seen in previous studies of ventricular assist devices. The study was not powered for a specific analysis of the adverse events.

6.1.4 Secondary Objectives

Secondary objectives were collected which included the following: re-operations, clinical reliability, functional status, quality of life, neurocognitive evaluation and post-explant follow-up.

Reoperations

Re-operations that were performed for any reason were captured as a secondary objective. In the Primary Cohort, 63% (79/126) of the patients had a re-operation. The majority (56%) of these events took place within 30 days of implant and was due to bleeding or delayed chest closure. Three patients received HMII pump replacements within 30 days of implant. Twenty-one (21%) percent of the re-operation events took place after 30 days post implant. Abdominal incision and drainage, RVAD placement or removal; dialysis catheter placement and driveline/pocket revision accounted for the majority of these events. Three patients received HMII pump replacements after 30 days post implant. As shown in **Table 8**, the incidence of reoperations was similar in both the CAP and Small BSA cohorts. The major reasons requiring reoperations were also similar to those observed in the Primary Study Cohort.

	Primary Study Cohort (n=126)	CAP Cohort (n=58	Small BSA Cohort (n=10)	Aggregate Data Cohort (n=194)
Patients having reoperations	79 (63%)	36 (58%)	7 (70%)	122 (63%)
Reoperations within 30 days of implant	56%	55%	60%	56%

Table 8 Incidence and Timing of Reoperations

Clinical Reliability

During the clinical study there were 78 reports of confirmed malfunctions in 194 patients having a median support duration of 131 days (see Sections 6.1.2 and 6.2.2, *Patient Population,* for more information on the 194 patients). Forty-four percent (44%, 34/78) involved implanted system components (i.e., pump and cannulae) and 56% (44/78) involved external system components (i.e. controllers, monitors, batteries, etc). Ten of the malfunctions of the implanted system components were classified as serious adverse events (i.e. resulted in death or permanent disability, or required prolonged hospitalization). These ten reports included percutaneous lead separation (4), pump thrombosis (3), inflow cannula twists (2) and outflow conduit leakage (1). Seven malfunctions of the external system components were also classified as serious adverse events, including damaged printed circuit boards in the System Controller (5), power base unit cable breakdown (1) and inadequate battery capacity (1).

Estimated clinical reliability of the HeartMate II LVAS blood pump, based on the bridge-to-transplantation study, is summarized in **Table 9**. Clinical reliability is estimated based on a Weibull analysis of the 10 malfunctions reported above (please note that 4 of these 10 events involved system components, which were not evaluated in the in vitro reliability test: percutaneous lead separation (3), and outflow conduit leakage (1).

Lower, One-Sided 80% Confidence Limit on Reliability R(t)	
Months	**Reliability**
6	0.932
12	0.896
24	0.833

Table 9 Estimated Clinical HeartMate II LVAD Reliability

The clinical experience over five years of clinical trials (both bridge–to-transplantation and destination therapy) and commercial use outside of the US has shown that wear and fatigue of the percutaneous lead connecting the HeartMate II LVAS blood pump to the external System Controller may result in damage that has the potential to interrupt pump function that may require a re-operation to replace the pump or result in death. The need for pump replacement due to percutaneous lead damage has occurred after implant durations ranging from 6 to 38 months of HeartMate II LVAS support. The estimated probability of the need for pump replacement due to percutaneous lead damage according to this analysis is 1.3% at 12 months, 6.5% at 24 months and 11.4% at 36 months.

Functional Status

Functional status was evaluated based on NYHA class assessments and 6-minute walk tests as summarized in **Figure 4** and **Figure 5**. These measures were obtained at baseline, 1 month, 3 months and 6 months (study outcome). Despite major heart surgery and adverse events, HeartMate II patients appeared to have improved functional capacity.

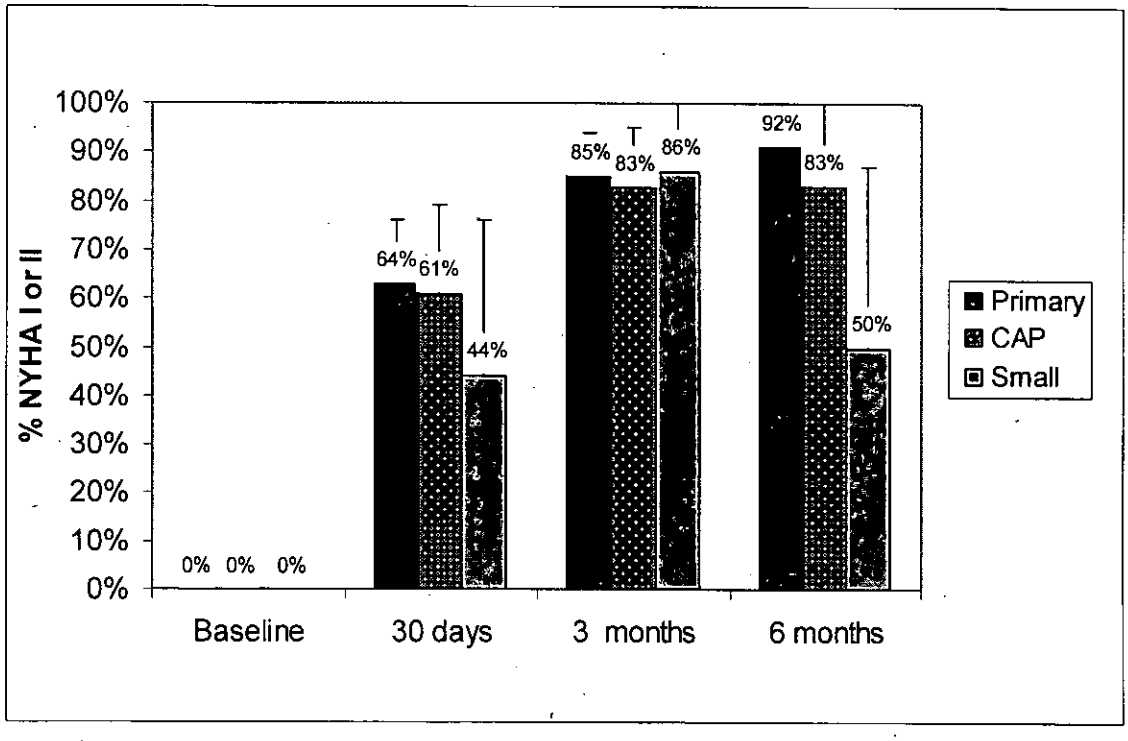


Figure 4 NYHA Class Over Time
(Error Bars = Standard Deviation)

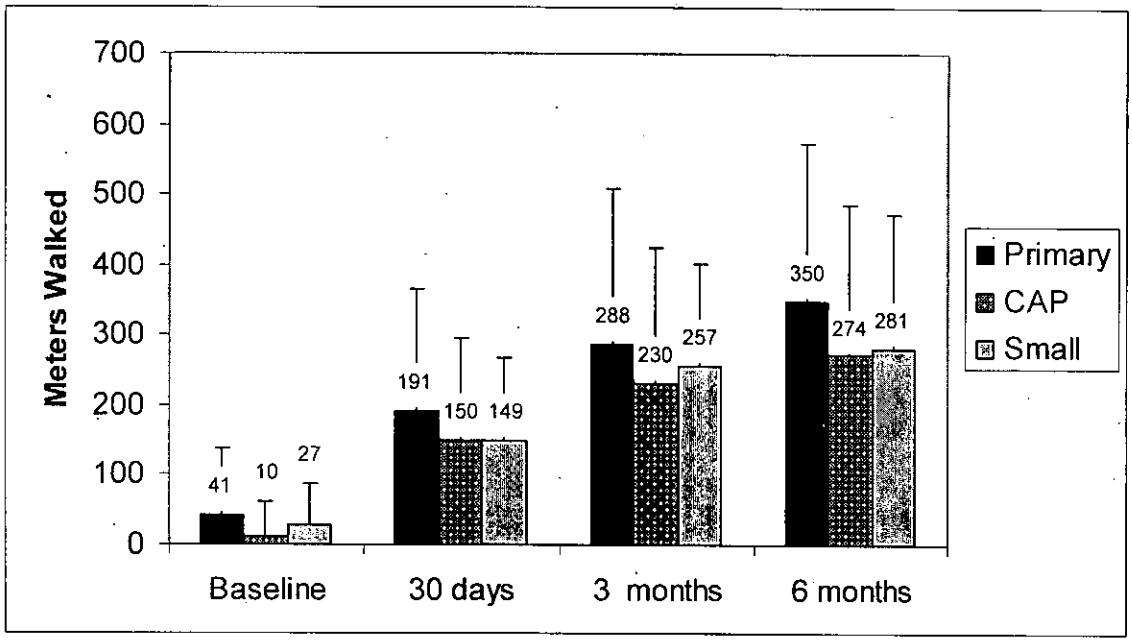
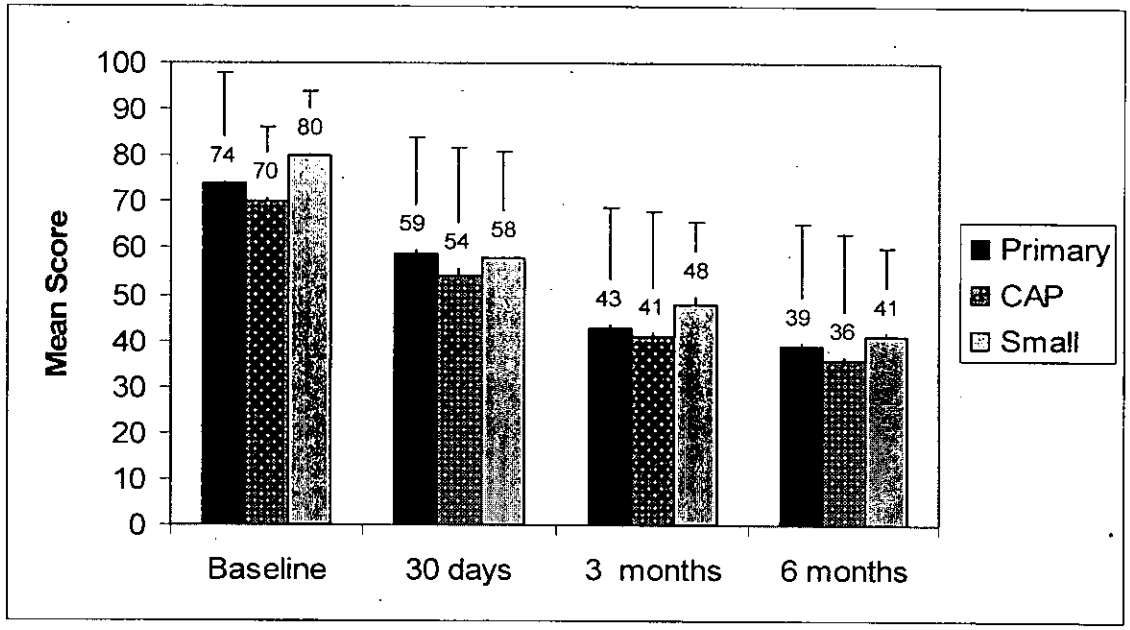


Figure 5 Summary of Six-Minute Walk Over Time
(Error Bars = Standard Deviation)

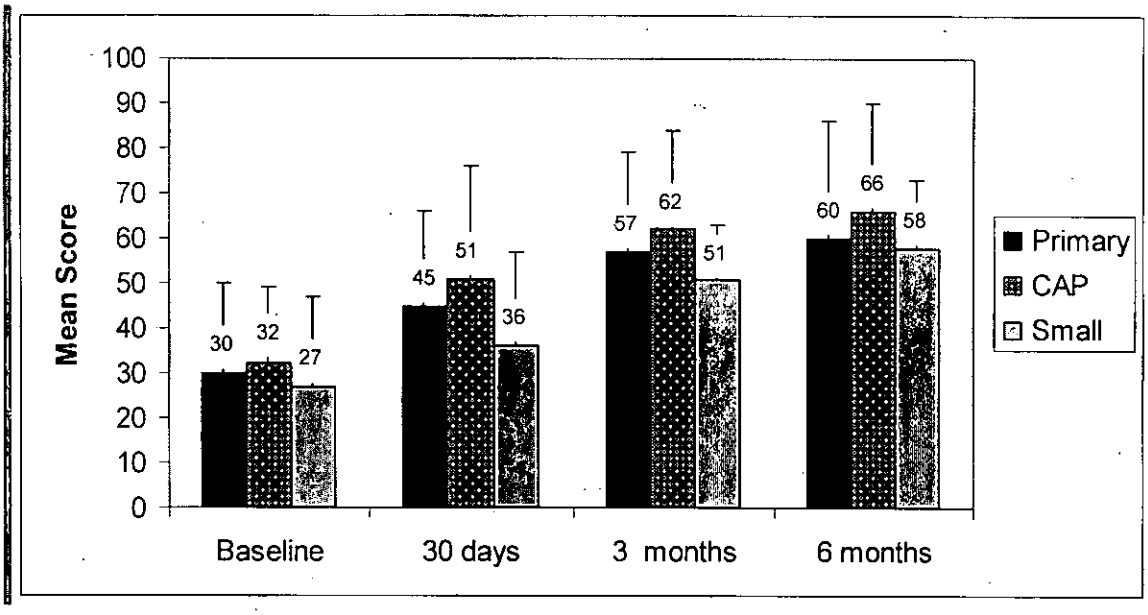
Quality of Life

Quality of life was measured via the Minnesota Living with Heart Failure Questionnaire (MLHF) and Kansas City Cardiomyopathy Questionnaire (KCCQ) as summarized in the **Figure 6** and **Figure 7**, below. These measures were obtained at baseline, 1 month, 3 months and 6 months (study outcome). Despite major heart surgery and adverse events, HeartMate II patients appeared to have improved quality of life.



Note: A lower score indicates better quality of life.

Figure 6 Minnesota Living with Heart Failure (MLHF) Questionnaire (Error Bars = Standard Deviation)



Note: A higher score indicates better quality of life.

Figure 7 Kansas City Cardiomyopathy Questionnaire (KCCQ) (Error Bars = Standard Deviation)

Neurocognitive Evaluations

Neurocognitive evaluations were performed in 11 of the 33 study sites. Eight standard neurocognitive measures with ten procedures were administered at baseline (1 month post-implant), 3 and 6 months post-implant. The tests surveyed cognitive domains involving memory, language, abstract/executive functions, visual/special perception and processing speed. Because of the small sample size (n=86), it is difficult to draw conclusions; however, important trends were seen. There was no significant cognitive decline in patients assessed between baseline and the 3 month or 6 month interval. There were significant improvements in cognitive test performance at 3 and 6 months over baseline for auditory memory, visual memory delay and processing speed. The majority of the cognitive test performance improvement was observed in the first 3 months post implant, with less change seen over extended follow-up intervals. As expected, most of the neurocognitive adverse events occurred at baseline and are likely due to cognitive instability shortly after implant. Over time, as the patients stabilized, neurocognitive functions improved and the incidence of adverse events declined.

Post-Explant Follow Up

Cohort	# Pts Transplanted (or recovered)	# Alive at 30 days post explant	% Alive at 30 days post explant
Primary	72 (3)	73	97%
CAP	33 (2)	35	100%
Small	7	5	71%
Aggregate Data	112 (5)	113	97%

Table 10 30-Day Post Explant Survival as of September 14, 2007

Cohort	# Pts Transplanted (or recovered)	# Alive at 1 Year post explant	% Alive at 1 year post explant
Primary	58 (2)	51 (2)	88%
CAP	7	7	100%
Small	4	2	50%
Aggregate Data	69 (2)	60 (2)	87%

Table 11 One-Year Post Explant Survival as of September 14, 2007

Gender Analysis

A *post hoc* analysis of the aggregate data for variations associated with gender was performed. Of the 194 patients who were followed to a study outcome or, if ongoing on HeartMate II LVAS support, for at least a year, the majority were male (77% males vs. 23% females). Some statistically significant differences were observed in some baseline hemodynamic and biochemistry parameters, but they are not considered to be clinically significant. Women were observed to have a higher incidence of strokes (18% vs. 6%), but the strokes did not have a significant effect on their overall survival compared with men. Trends toward a higher incidence of bleeding and infection events were observed in females than males. Nonetheless, the sample size of men compared to women (150 vs. 44) makes it difficult to draw any conclusions regarding differences in safety profile of the device between men and women. The results show that there do not appear to be differences with primary study outcome, NYHA Classification, 6 minute walk, MLWHF, and KCCQ assessments.

6.2 Destination Therapy Study Overview

The objective of the study was to determine the safety and efficacy of the HeartMate II as Destination Therapy (DT) in end-stage heart failure patients who do not qualify for cardiac transplantation. Efficacy was evaluated by comparing a composite endpoint that included survival at two years between the HeartMate II and the HeartMate XVE, the only mechanical circulatory support device approved for this indication for use. The safety of the HeartMate II was documented by the incidence of adverse events and the incidence of device malfunctions and failures.

NOTE: Thoratec reserves the right to change specifications without notice.

In addition, a number of secondary objectives were evaluated during the study, including functional status and quality of life, reoperations and neuro-cognitive assessments.

6.2.1 Study Design

The Destination Therapy (DT) Pivotal trial was a prospective, randomized, unblinded, non-inferiority evaluation of the HeartMate II in end-stage heart failure patients who are not eligible for cardiac transplantation and are refractory to optimal medical therapy. The statistical analysis plan in the study protocol specified testing for superiority once non-inferiority was established. Patients were randomly assigned to treatment with the HeartMate XVE (control group) or to treatment with the HeartMate II. Two patients were randomized to the HeartMate II for every one patient randomized to the HeartMate XVE. Two hundred patients were enrolled into the Primary Study Cohort (134 HeartMate II and 66 HeartMate XVE) at 38 investigational sites from March 2005 to May 2007.

This study also enrolled patients into four additional study cohorts. Refer to **Figure 8** for a summary of the cohorts and number of patients enrolled.

- Small BSA Cohort: Patients who had a BSA of less than $1.5m^2$ and therefore, could not be randomized to the HeartMate XVE due to its size.
- XVE Exchange Cohort: Destination Therapy patients who received the HeartMate II as a replacement for a failed HeartMate XVE originally implanted under commercial use.
- Randomized Continued Access Protocol (CAP) Cohort: Upon completing enrollment in the Primary Study Cohort, patient enrollment continued under CAP, using the same study protocol as the Primary Study Cohort.

- Randomization Deviation Cohort. This cohort included patients that had a BSA > $1.5m^2$ but could not be randomized to the HeartMate XVE due to their body habitus or other complications.

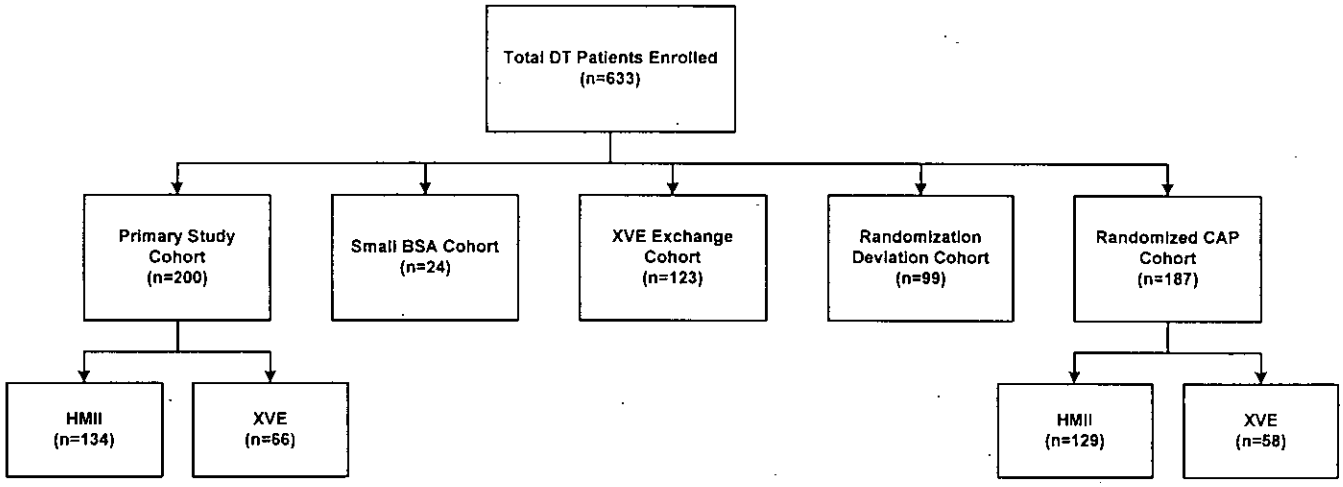


Figure 8 Total Number of Patients Enrolled in Each Cohort (as of December 15, 2008)

The study had two oversight committees: a Clinical Events Committee (CEC), which adjudicated all adverse events and deaths, and a Data and Safety Monitoring Board (DSMB), which reviewed the study data periodically to ensure that the study was safe to continue.

The primary endpoint of the trial was a composite endpoint: two year survival free of stroke resulting in a Rankin score > 3, or reoperation to repair or replace the device. Patients were considered a success if they achieved the composite endpoint and a failure if they did not. Patients who were urgently transplanted due to device failure were considered a failure. Patients who were electively transplanted after reversal of a pre-enrollment co-morbidity were followed and considered a success if they achieved two years of survival from the day of their VAD implant without experiencing a stroke resulting in a Rankin score > 3. The HeartMate II was judged a success if the proportion of HeartMate II patients who achieved the composite endpoint was equal to or better than the HeartMate XVE comparison group.

6.2.2 Primary Study Cohort Patient Population

The HeartMate II was implanted as Destination Therapy in patients who were not candidates for cardiac transplantation. Patients were ineligible for transplant primarily due to age (28%), recent history of cancer (9%), obesity (7%) and substance abuse or insufficient social support (7%). The patients' age ranged from 26 to 81 years, with a median of 64 years. The majority of patients were caucasian males with ischemic heart disease. No significant differences were seen in age, BSA, body mass index (BMI), etiology or ethnicity between the HeartMate II and HeartMate XVE groups. Despite randomization, the HeartMate II arm included a significantly larger number of females then the HeartMate XVE arm. A gender analysis was performed and determined that there was no influence on the treatment effect (refer to the Gender Analysis Section at the end of this document). Patient demographics are presented in **Table 12**.

	HM II (n=134)	XVE (n=66)	P*
Age (years)**	64 (26-79)	65 (29-81)	0.8125
Etiology	66% Ischemic	68% Ischemic	0.7526
Gender	81% Male 19% Female	92% Male 8% Female	0.0369
BSA (m^2)**	2.0 (1.6-2.8)	2.0 (1.6-2.8)	0.5438
BMI (kg/m^2)**	27.4 (18.0-43.4)	27.9 (18.2-40.1)	0.9913

* Unpaired t-test or Fisher's exact test, as appropriate
**median and range

Table 12 Primary Study Cohort: Baseline Demographics

The baseline laboratory assessments, hemodynamic values and cardiovascular history did not reveal any statistically significant differences between the HeartMate II and HeartMate XVE group. Of note in the cardiovascular history is that overall, 83% of the patients entered the study with implantable cardiac defibrillators (ICD) and 16% of the patients had a history of stroke (refer to **Table 13**). Overall, 79% of the patients were on inotropes at baseline, 23% on intra-aortic balloon pump (IABP) and 8% on mechanical ventilation. The similarity in baseline characteristics indicates that the two treatment arms are comparable.

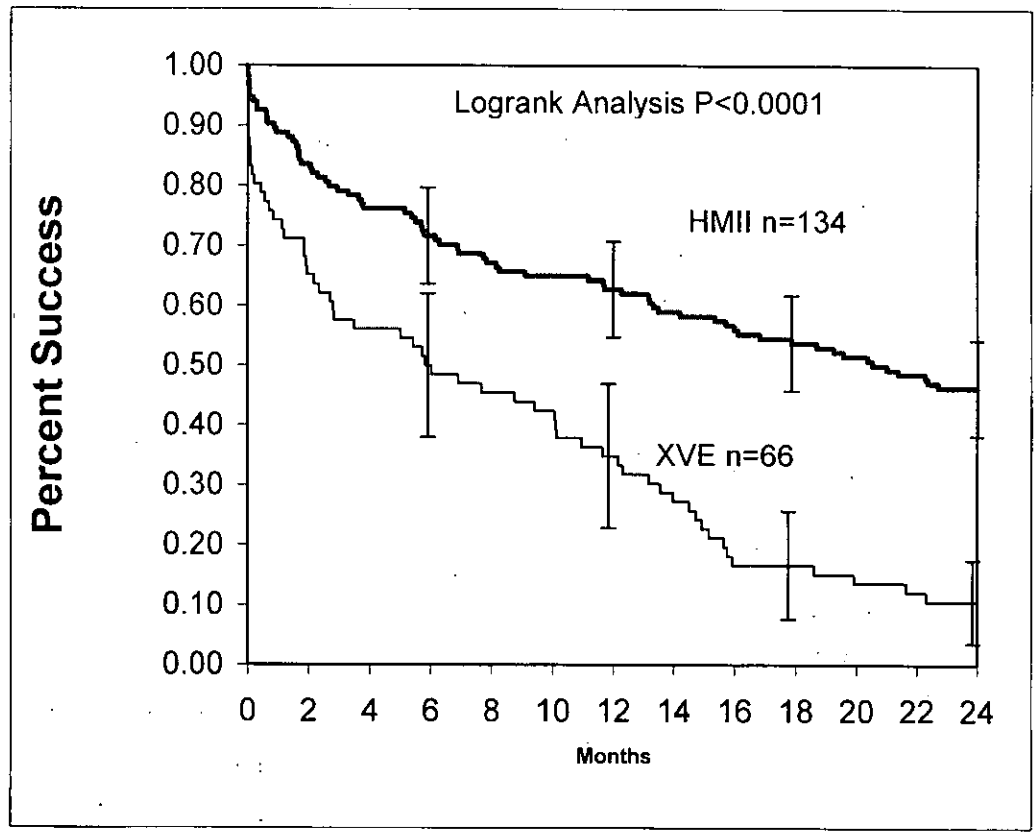
	HM II (n=134)		XVE (n=66)		
Cardiovascular	**# Pts**	**% Pts**	**# Pts**	**% Pts**	**P***
Arrhythmias	115	86%	55	83%	0.6762
Ventricular Arrhythmias	65	49%	38	58%	0.2337
Ventricular Pacing	105	78%	45	68%	0.1225
Biventricular Pacing	85	63%	39	59%	0.6423
Implantable Cardiac Defibrillator (ICD)	111	83%	52	79%	0.5619
Stroke	21	16%	11	17%	0.8403

*Fisher's exact test

Table 13 – Primary Study Cohort: Baseline Cardiovascular History

6.2.3 Primary Study Endpoint

The primary endpoint of the trial was a composite endpoint: two year survival free of stroke resulting in a Rankin score > 3 or reoperation to repair or replace the device. Complete follow-up was obtained for all 200 Primary Study Cohort patients. The results of the analysis demonstrated overwhelming statistical superiority of the HeartMate II ($p<0.0001$). Forty-six percent (62/134) of the patients randomized into the HeartMate II cohort successfully achieved the composite endpoint, while only 11% (7/66) of patients randomized into the HeartMate XVE cohort did so. These analyses are displayed in the Kaplan-Meier analysis in **Figure 9** and **Table 14**, and the Final Analysis Results in **Figure 10** and **Table 15**.



Error bars = 95% confidence interval

Figure 9 Primary Study Cohort (Intent to Treat): Kaplan-Meier of Composite Endpoint; Survival Free of Stroke (Rankin score >3) or Reoperation to Repair or Replace the Pump

HMII							
	Time Interval (Months)						
	0 - 1	1 - 3	3 - 6	6 - 9	9 - 12	12 - 18	18 - 24
Number of patients starting interval	134	119	106	96	88	84	72
Number of patients who had event this interval	15	13	10	8	4	12	10
Number of cumulative patient events	15	28	38	46	50	62	72
Number of patients censored in interval	0	0	0	0	0	0	0
Number of cumulative censored patients	0	0	0	0	0	0	0
Probability of surviving interval event free	0.888	0.791	0.716	0.657	0.627	0.537	0.463
+/- 95% Confidence Limit at end of interval	0.05	0.07	0.08	0.08	0.08	0.08	0.08
XVE							
	Time Interval (Months)						
	0 - 1	1 - 3	3 - 6	6 - 9	9 - 12	12 - 18	18 - 24
Number of patients starting interval	66	49	38	33	29	23	11
Number of patients who had event this interval	17	11	5	4	6	12	4
Number of cumulative patient events	17	28	33	37	43	55	59
Number of patients censored in interval	0	0	0	0	0	0	0
Number of cumulative censored patients	0	0	0	0	0	0	0
Probability of surviving interval event free	0.742	0.576	0.500	0.439	0.349	0.167	0.106
+/- 95% Confidence Limit at end of interval	0.11	0.12	0.12	0.12	0.12	0.09	0.07

Events = death, withdrawal from study, stroke (Rankin >3) or reoperation to repair or replace the pump, whichever occurs first

Table 14 Primary Study Cohort (Intent to Treat): Kaplan-Meier of Composite Endpoint; Survival Free of Stroke (Rankin score >3) or Reoperation to Repair or Replace the Pump

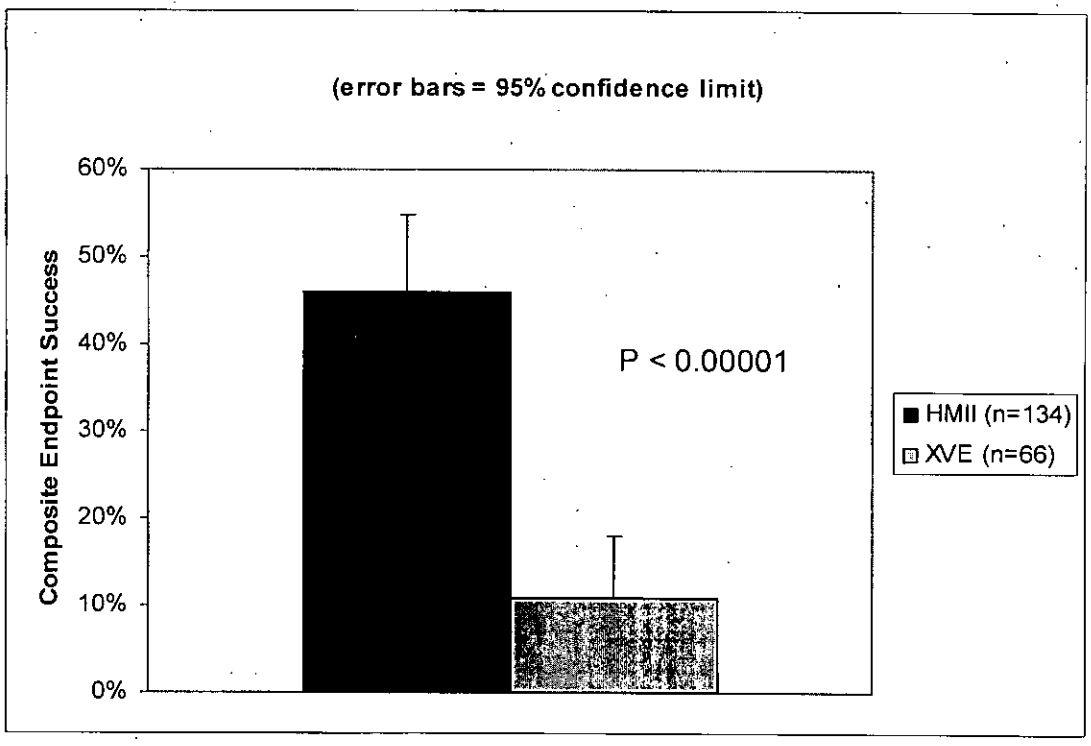


Figure 10 Primary Study Cohort (Intent To Treat): Final Analysis Results

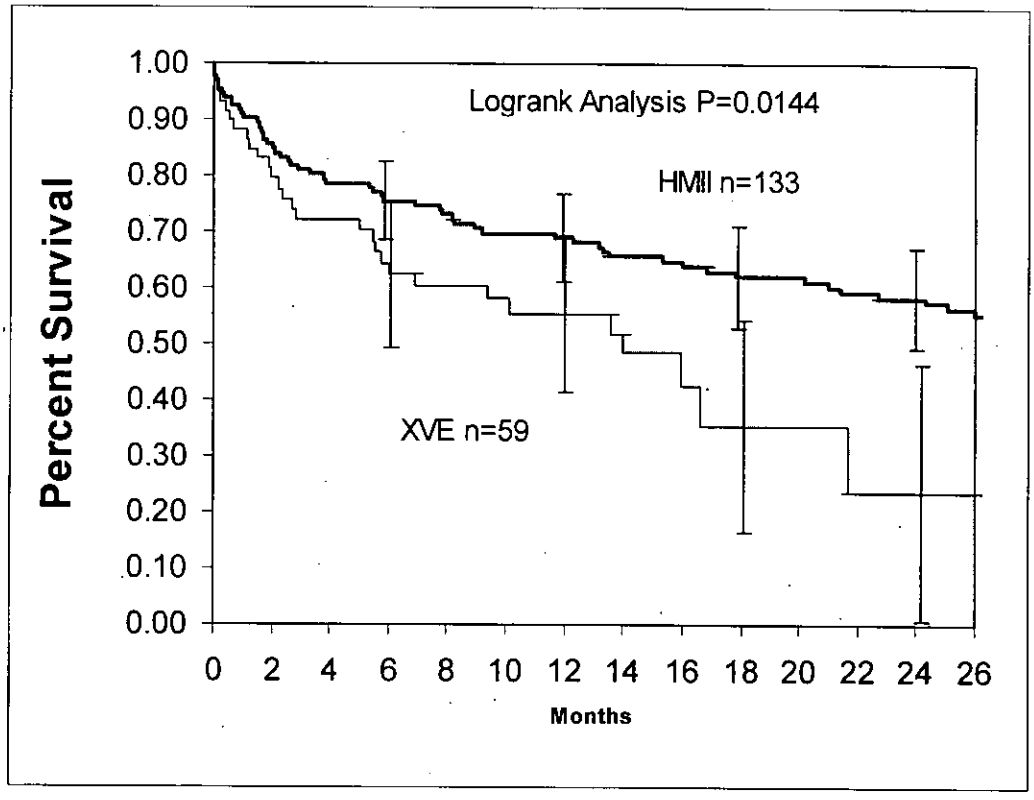
Randomized to	n	Implanted	Success	95% Confidence Interval	P*	Difference between Proportions (95%Confidence Interval)
HM II	134	131[1]	62/134 (46%)	38 - 55%	0.000000246	35.7% (24.5 - 46.9%)
XVE	66	61[2]	7/66 (11%)	3 - 18%		
Total	200	192				

*Fisher's exact test
[1] One patient randomized to HM II but received XVE
[2] Three patients randomized to XVE but received HM II

Table 15 Primary Study Cohort (Intent To Treat): Final Analysis Results

Overall Survival

Figure 11 and **Table 16** below present the overall survival in an As Treated analysis. Patients who were transplanted, explanted or had their HeartMate XVE exchanged to a HeartMate II were censored at that time in the analysis. As seen in **Figure 11** below, there is a statistically significant difference in overall As Treated survival favoring the HeartMate II when compared to the HeartMate XVE. Patients supported with the HeartMate II have a two-year predicted survival of 58% compared to 24% for patients supported with the HeartMate XVE. **Table 16** below provides the details of the analysis including the number of patients at each interval.



Error bars = 95% confidence limits

Figure 11 Primary Study Cohort (As Treated): Kaplan-Meier of Overall Survival

HMII							
	Time Interval (Months)						
	0 - 1	1 - 3	3 - 6	6 - 9	9 - 12	12 - 18	18 - 24
Number of patients starting interval	133	121	105	95	86	82	69
Number of patients who died this interval	12	13	7	6	2	8	4
Number of cumulative patient deaths	12	25	32	38	40	48	52
Number of patients censored in interval	0	3	3	3	2	5	3
Number of cumulative censored patients	0	3	6	9	11	16	19
Probability of surviving interval	0.091	0.810	0.755	0.706	0.690	0.620	0.583
+/- 95% Confidence Limit at end of interval	0.05	0.07	0.07	0.08	0.08	0.09	0.09
XVE							
	Time Interval (Months)						
	0 - 1	1 - 3	3 - 6	6 - 9	9 - 12	12 - 18	18 - 24
Number of patients starting interval	59	52	39	32	26	19	5
Number of patients who died this interval	7	9	4	2	2	4	1
Number of cumulative patient deaths	7	16	20	22	24	28	29
Number of patients censored in interval	0	4	3	4	5	10	2
Number of cumulative censored patients	0	4	7	11	16	26	28
Probability of surviving interval	0.881	0.722	0.644	0.604	0.554	0.354	0.236
+/- 95% Confidence Limit at end of interval	0.08	0.12	0.13	0.13	0.14	0.19	0.23

Censored = at time of transplant, explant, or crossover from XVE to HM II

Table 16 Primary Study Cohort (As Treated): Kaplan-Meier of Overall Survival

Safety: Adverse Events

No new adverse events were observed in the HeartMate II LVAS study that have not been seen in previous studies of ventricular assist devices. The study was not powered for a specific analysis of the adverse events. The incidence of all adverse events and serious adverse events are presented in **Table 17** and **Table 18**, respectively.

To take into account differences in patient durations, adverse events were normalized to events per patient-year and analyzed using Poisson regression to obtain risk ratios with 95% confidence intervals. **Table 19** and **Table 20** present the results of this As Treated analysis for all adverse events and serious adverse events, respectively. As evidenced in **Table 19** and **Table 20**, the HeartMate II patients experienced significantly reduced rates of local infections, pump pocket infections, sepsis, and right heart failure as evidenced by inotrope use, respiratory failure and renal failure events per patient-year than the HeartMate XVE patients. Patients implanted with the HeartMate XVE did not experience a significant advantage over HeartMate II patients in any adverse event.

As shown in **Table 19**, the rate of confirmed malfunctions was the same for both the HeartMate II and the HeartMate XVE, 0.53 events/patient-year. However, as shown in **Table 20** the rate of serious confirmed malfunctions (those resulting in death or serious injury) was much less for the HeartMate II. The risk ratio, while

not statistically significant, was 0.59, favoring the HeartMate II. The types of serious malfunctions were also different; nearly all of the serious malfunctions of the HeartMate XVE involved the implanted pump, but over half of the serious malfunctions of the HeartMate II involved external components that are readily replaceable.

	HM II (n=133)					HM XVE (n=59)				
	# Pts	% Pts	UCL*	LCL**	# Events	# Pts	% Pts	UCL*	LCL**	# Events
Bleeding	118	89%	94%	83%	399	51	86%	95%	78%	113
Bleeding requiring surgery	40	30%	38%	22%	50	9	15%	24%	6%	12
Stroke	24	18%	25%	12%	27	8	14%	22%	5%	9
Peri-operative (≤POD2)	3	2%	5%	0%	3	1	2%	5%	0%	1
Post-operative (>POD2)	21	16%	22%	10%	24	7	12%	20%	4%	8
Other Neurological***	29	22%	29%	15%	35	10	17%	27%	7%	12
Local Infection	65	49%	57%	40%	160	27	46%	58%	33%	55
Drive Line Infection	42	32%	39%	24%	80	16	27%	38%	16%	25
Pocket Infection	12	9%	14%	4%	19	8	14%	22%	5%	10
Pump Housing	1	1%	2%	0%	1	2	3%	8%	0%	2
Sepsis	48	36%	44%	28%	81	26	44%	57%	31%	46
Right Heart Failure	31	23%	30%	16%	34	19	32%	44%	20%	22
Inotropes Only	27	20%	27%	13%	29	16	27%	38%	16%	19
RVAD	5	4%	7%	1%	5	3	5%	11%	0%	3
Peripheral TE	14	11%	16%	5%	21	8	14%	22%	5%	8
Respiratory Failure	50	38%	46%	29%	65	24	41%	53%	28%	33
Cardiac Arrhythmias	75	56%	65%	48%	145	35	59%	72%	47%	54
Renal Failure	21	16%	22%	10%	21	14	24%	35%	13%	14
Hepatic Dysfunction	3	2%	5%	0%	3	0	0%	0%	0%	0
Device Thrombosis	5	4%	7%	1%	5	0	0%	0%	0%	0
Hemolysis	5	4%	7%	1%	5	0	0%	0%	0%	0
Psychological	8	6%	10%	2%	11	4	7%	13%	0%	4
Myocardial Infarction	0	0%	0%	0%	0	1	2%	5%	0%	1
Confirmed Malfunctions	58	44%	52%	35%	112	17	29%	40%	17%	22

*Upper 95% confidence limit
** Lower 95% confidence limit
***Includes transient ischemic attacks (TIA) and non-stroke neurological events

Table 17 Primary Study Cohort (As Treated): All Adverse Events

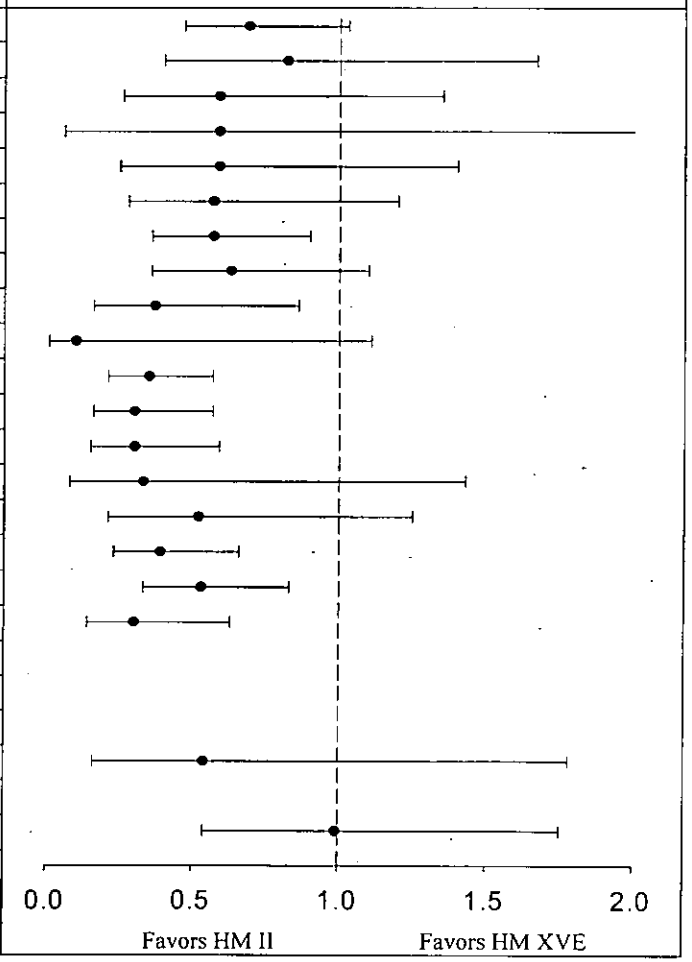
	HM II (n=133)					HM XVE (n=59)				
	# Pts	% Pts	UCL*	LCL**	# Events	# Pts	% Pts	UCL*	LCL**	# Events
Bleeding	102	77%	84%	70%	278	41	69%	81%	58%	70
Bleeding requiring surgery	40	30%	38%	22%	50	9	15%	24%	6%	12
Stroke	24	18%	25%	12%	27	8	14%	22%	5%	9
Peri-operative (≤POD2)	3	2%	5%	0%	3	1	2%	5%	0%	1
Post-operative (>POD2)	21	16%	22%	10%	24	7	12%	20%	4%	8
Other Neurological***	27	20%	27%	13%	32	9	15%	24%	6%	11
Local Infection	40	30%	38%	22%	60	19	32%	44%	20%	30
Drive Line Infection	39	29%	37%	22%	75	14	24%	35%	13%	22
Pocket Infection	12	9%	14%	4%	19	8	14%	22%	5%	10
Pump Housing	1	1%	2%	0%	1	2	3%	8%	0%	2
Sepsis	48	36%	44%	28%	80	26	44%	57%	31%	45
Right Heart Failure	31	23%	30%	16%	34	19	32%	44%	20%	22
Inotropes Only	27	20%	27%	13%	29	16	27%	38%	16%	19
RVAD	5	4%	7%	1%	5	3	5%	11%	0%	3
Peripheral TE	14	11%	16%	5%	21	6	10%	18%	2%	6
Respiratory Failure	47	35%	43%	27%	61	24	41%	53%	28%	33
Cardiac Arrhythmias	62	47%	55%	38%	110	21	36%	48%	23%	30
Renal Failure	21	16%	22%	10%	21	14	24%	35%	13%	14
Hepatic Dysfunction	3	2%	5%	0%	3	0	0%	0%	0%	0
Device Thrombosis	5	4%	7%	1%	5	0	0%	0%	0%	0
Hemolysis	5	4%	7%	1%	5	0	0%	0%	0%	0
Psychological	4	3%	6%	0%	4	0	0%	0%	0%	0
Myocardial Infarction	0	0%	0%	0%	0	1	2%	5%	0%	1
Confirmed Malfunctions	30	23%	30%	15%	39	12	20%	31%	10%	13

*Upper 95% confidence limit
** Lower 95% confidence limit
***Includes transient ischemic attacks (TIA) and non-stroke neurological events

Table 18 Primary Study Cohort (As Treated): Serious Adverse Events

Table 19 – Primary Study Cohort (As Treated): All Adverse Events per Patient-year

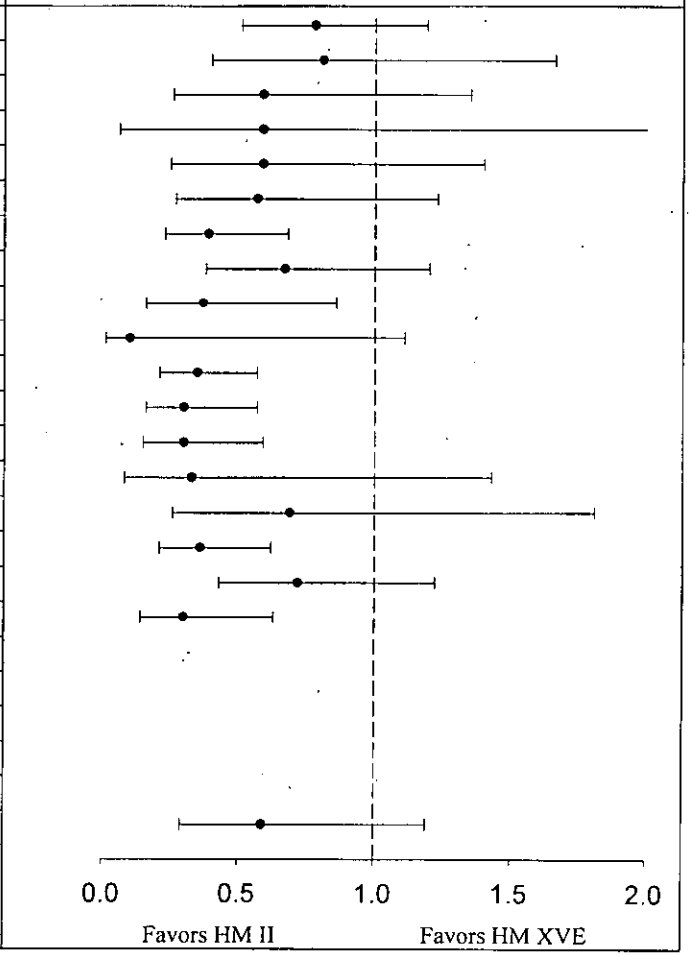
	HM II (n=133) 210 pt-years	HM XVE (n=59) 41 pt-years		
Event	**Events/pt-yr**	**Events/pt-yr**	**Risk Ratio**	**95% Confidence Interval****
Bleeding	1.90	2.74	0.69	
Bleeding requiring surgery	0.24	0.29	0.82	
Stroke	0.13	0.22	0.59	
Peri-operative (≤POD2)	0.01	0.10	0.59	
Post-operative (>POD2)	0.11	0.12	0.59	
Other Neurological*	0.17	0.29	0.57	
Local Infection	0.76	1.33	0.57	
Drive Line Infection	0.38	0.61	0.63	
Pocket Infection	0.09	0.24	0.37	
Pump Housing	0.00	0.05	0.10	
Sepsis	0.39	1.11	0.35	
Right Heart Failure	0.16	0.53	0.30	
Inotropes Only	0.14	0.46	0.30	
RVAD	0.02	0.07	0.33	
Peripheral TE	0.10	0.19	0.52	
Respiratory Failure	0.31	0.80	0.39	
Cardiac Arrhythmias	0.69	1.31	0.53	
Renal Failure	0.10	0.34	0.30	
Hepatic Dysfunction	0.01	0.00	-	
Device Thrombosis	0.02	0.00	-	
Hemolysis	0.02	0.00	-	
Psychological	0.05	0.10	0.54	
Myocardial Infarction	0.00	0.02	-	
Confirmed Malfunctions	0.53	0.53	0.99	



*Includes transient ischemic attacks (TIA) and non-stroke neurological events.
**No adjustments made for multiplicity; no conclusions may be drawn regarding statistical significance

Table 20 – Primary Study Cohort (As Treated): All Serious Adverse Events

	HM II (n=133) 210 pt-years	HM XVE (n=59) 41 pt-years		
Event	**Events/pt-yr**	**Events/pt-yr**	**Risk Ratio**	**95% Confidence Interval****
Bleeding	1.32	1.69	0.78	
Bleeding requiring surgery	0.24	0.29	0.81	
Stroke	0.13	0.22	0.59	
Peri-operative (≤POD2)	0.01	0.02	0.59	
Post-operative (>POD2)	0.11	0.19	0.59	
Other Neurological*	0.16	0.27	0.57	
Local Infection	0.29	0.73	0.39	
Drive Line Infection	0.36	0.53	0.67	
Pocket Infection	0.09	0.24	0.37	
Pump Housing	0.00	0.05	0.10	
Sepsis	0.38	1.09	0.35	
Right Heart Failure	0.16	0.53	0.30	
Inotropes Only	0.14	0.46	0.30	
RVAD	0.02	0.07	0.33	
Peripheral TE	0.10	0.15	0.69	
Respiratory Failure	0.29	0.80	0.36	
Cardiac Arrhythmias	0.52	0.73	0.72	
Renal Failure	0.10	0.34	0.30	
Hepatic Dysfunction	0.01	0.00	---	
Device Thrombosis	0.02	0.00	---	
Hemolysis	0.02	0.00	---	
Psychological	0.02	0.00	---	
Myocardial Infarction	0.00	0.02	---	
Confirmed Malfunctions	0.19	0.31	0.59	



*Includes transient ischemic attacks (TIA) and non-stroke neurological events.
**No adjustments made for multiplicity; no conclusions may be drawn regarding statistical significance

Reoperations

Reoperations include any return to the operating room for any reason following implant. Reoperations were device or patient related, such as driveline debridement or bleeding, and included routine surgeries, such as appendectomy and fracture repairs. As reflected in **Table 21**, the incidence of reoperations was similar between the groups. When normalized to events per patient-year, there is a much lower rate of reoperations per patient-year in the HeartMate II group (risk ratio 0.53).

	# pts	# pts with reoperations	% pts with reoperations	# events	Reops/ pt-yr	Risk Ratio
HMII	133	106	80%	325	1.55	0.53
XVE	59	43	73%	120	2.91	

Table 21 Primary Study Cohort (As Treated): Reoperations

Clinical Reliability

Clinical reliability was evaluated by taking into account all HeartMate II study experience, regardless of study cohort. One hundred and one (101) reports of suspected malfunctions related to the implanted components of the HeartMate II LVAS were received from the 509 HeartMate II patients enrolled into the Destination Therapy clinical study. Eighty-five percent of those reports were related to the percutaneous lead. There were 28 reports of malfunctions that resulted in hemodynamic compromise, reoperations for pump replacement, pump explantation, or death, 27 of which were related to the percutaneous lead. As shown in **Table 22**, reliability of the current configuration of the percutaneous lead is improved compared to the overall reliability, as a result of design modifications intended to reduce the most frequent failure modes.

Percutaneous Lead Configuration	Type of Malfunction	Reliability* at:		
		1 yr	2 yr	3 yr
All configurations	All malfunctions	.849	.615	.390
	Reoperation/Death	.959	.872	.752
Current Configuration**	All malfunctions	.954	.910	.868
	Reoperation/Death	.972	.946	.920

* Reliability estimates based on Weibull analysis
** At time of PMA approval

Table 22 – Percutaneous Lead Reliability (All Cohorts)

Functional Status, Quality of Life, and Neurocognitivie Measures

The secondary objectives that were studied included functional evaluations based on NYHA class, six-minute walk, and Metabolic Equivalents scores (METs). Quality of life (QoL) was measured via the Minnesota Living with Heart Failure Questionnaire (MLWHF) and Kansas City Cardiomyopathy Questionnaire (KCCQ). Neurocognitive evaluations were also performed. In summary,

significant improvement was seen in the quality of life scores and in functional status over baseline and over time through 12 months, as can be seen in **Figures 23 – 27** below. After 12 months, there were too few HeartMate XVE patients to analyze. An additional measure of QoL was time spent out of hospital. Once implanted, HeartMate II patients spent 87% of their support time out of hospital compared to 69% for patients implanted with the HeartMate XVE (As Treated analysis). No decline in neurocognitive function was observed, and trends towards improvement over time were observed for some neurocognitive measures.

In **Figures 23** through **27** the numbers of patients analyzed at each interval is shown above each bar. Error bars extending beyond the data bars in the figures denote 95% confidence intervals or standard deviation, as noted in each figure.

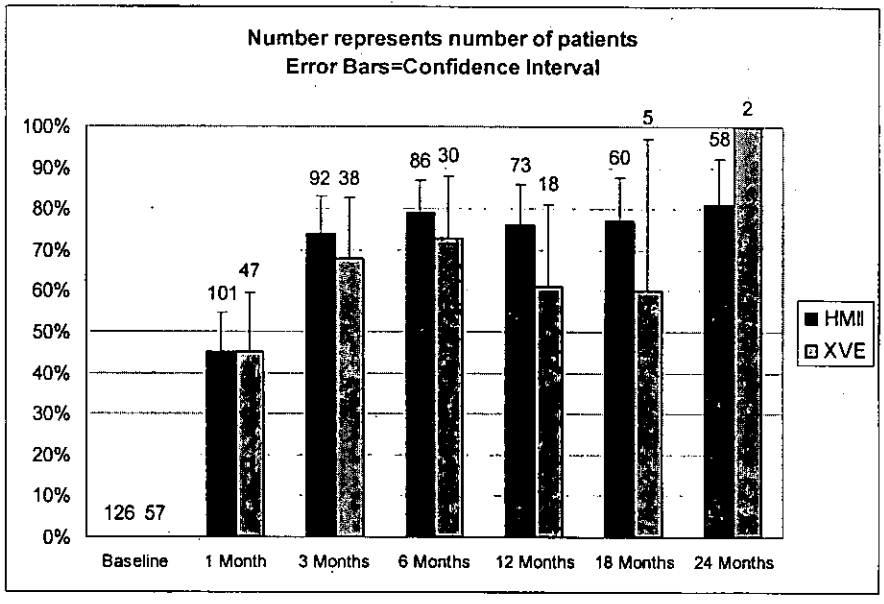


Figure 23 Primary Study Cohort (As Treated): NYHA Class I or II over Time

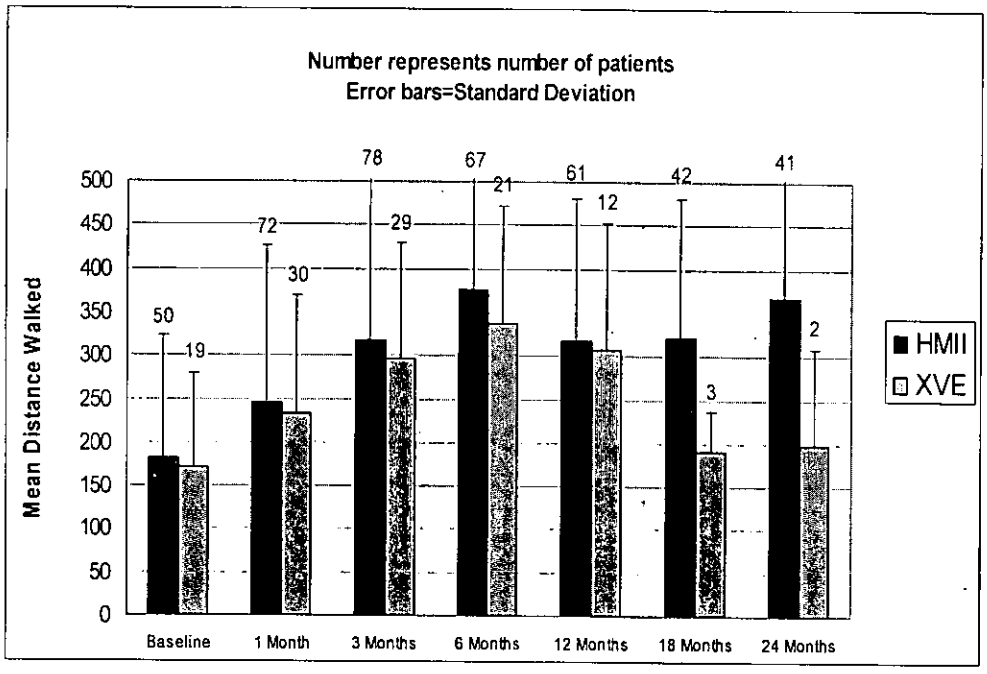


Figure 24 Primary Study Cohort (As Treated): Six Minute Walk; Meters Walked over Time

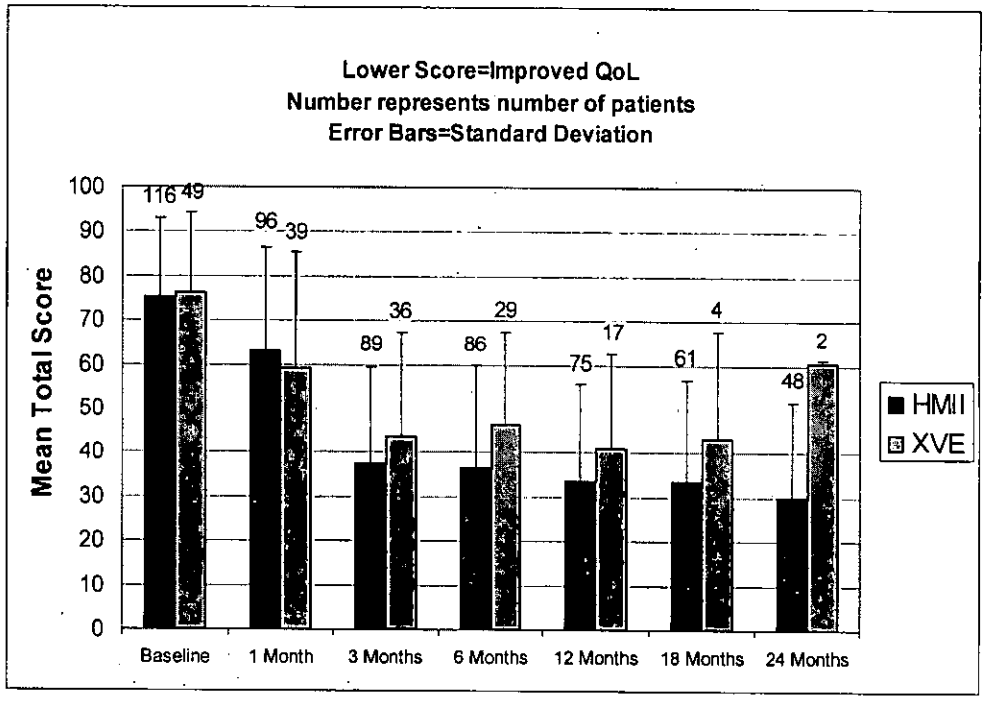


Figure 25 Primary Study Cohort (As Treated): MLWHF Scores over Time

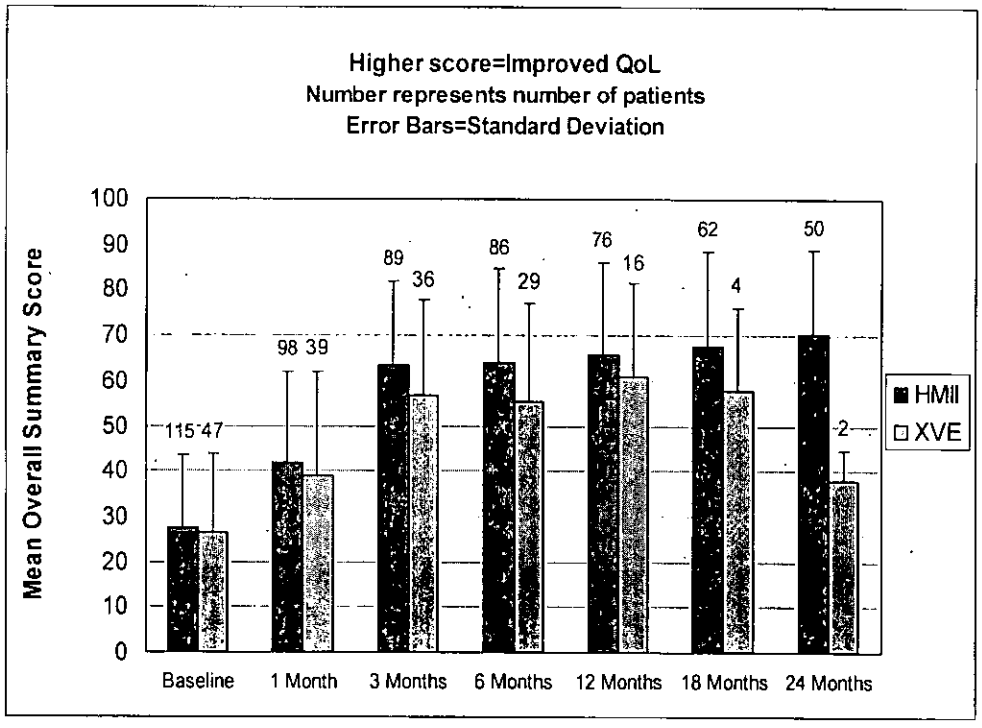


Figure 26 Primary Study Cohort (As Treated): KCCQ Overall Summary Score over Time

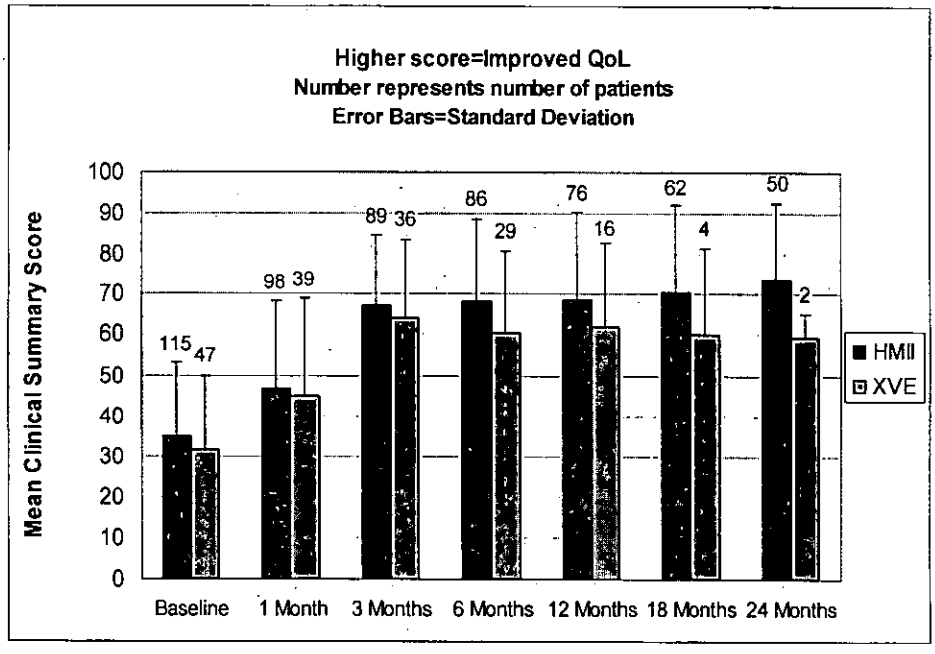


Figure 27 Primary Study Cohort (As Treated): KCCQ Clinical Summary Score over Time

Gender Analysis

An analysis was performed to determine if the treatment effect observed in the trial was influenced by the gender differences between treatment groups. In addition, Kaplan-Meier analyses were performed by gender to determine if the superior results obtained by patients supported with the HeartMate II were experienced by both males and females.

In the Primary Study Cohort, despite randomizing patients into treatment arms, 16% of patients randomized into the HeartMate II cohort were female compared to 8% in the HeartMate XVE cohort. This difference in gender was statistically significant (P=0.0369). Logistic regression was used to determine that this gender difference did not influence the treatment effect seen in the trial. A Kaplan–Meier analysis of the study's primary composite endpoint, stratified by gender, was limited due to the small number of females enrolled in the trial.

A *post hoc* analysis was conducted which included patients from other cohorts. Patients enrolled in the Primary Study Cohort were combined with patients randomized into the Continued Access Protocol (CAP) for the trial. This pooled cohort will be referred to as the Randomized Cohort. Sixteen (16 %) of patients randomized into the HeartMate II group were female, compared to ten percent (10 %) in the HeartMate XVE Cohort. This difference in gender was no longer significant (P=0.2094). The Randomized Cohort provided 54 female patients to evaluate. An analysis of baseline demographics and etiology demonstrated that the groups remained comparable.

A Kaplan-Meier analysis comparison of the Randomized Cohort males (222 HeartMate II versus 111 HeartMate XVE) and females (41 HeartMate II vs. 13 HeartMate XVE), of the study's primary composite endpoint resulted in a significant survival advantage ($p<0.0001$) for HeartMate II patients irrespective of gender. This analysis provides evidence that gender differences have not influenced the outcome results observed in the trial and that the superior results of the HeartMate II are shared by both males and females.

Adverse event rates between males who received a HeartMate II compared to males who received the HeartMate XVE were similar to overall study results for the Primary Study Cohort, with significant differences in adverse event rates favoring the males implanted with the HeartMate II. The same result was also true for females implanted with the HeartMate II.

A second *post hoc* analysis was performed to provide additional females by combining patients enrolled into the Small BSA Cohort (patients with BSA < $1.5m^2$) and the HeartMate II Randomization Deviation Cohort (patients with BSA ≥ $1.5m^2$ but who could not receive an HeartMate XVE due to body habitus or surgical issues) with the HeartMate II patients from the Randomized Cohort described above. This combined cohort included 286 males and 100 females, all supported with the HeartMate II. A Kaplan-Meier analysis of survival free of stroke (Rankin > 3) or reoperation to repair or replace the device resulted in no significant difference between males supported with the HeartMate II compared to females supported with the HeartMate II (p=0.2650).

Males supported with the HeartMate II had significantly better adverse event rates for local infection and peripheral thrombo-embolic events when compared to females

supported with the HeartMate II. The thrombo-embolic event rate was influenced by one female who had eight thrombo-embolic events to her lower extremities.

In conclusion, the gender analysis shows that the benefits and risks of the HeartMate II are similar for males and females and that the observed treatment effect was not influenced by gender.

Thoratec Corporation

HEARTMATE II® LEFT VENTRICULAR ASSIST SYSTEM (LVAS)

℞ Only

(Corporate Headquarters)
6035 Stoneridge Drive • Pleasanton, CA 94588 • USA
Tel. 925-847-8600 • Fax 925-847-8574
www.thoratec.com

Thoratec Europe Limited
(Authorized European Representative)
Burnett House
Lakeview Court • Ermine Business Park
Huntingdon, Cambs PE29 6UA UK
Tel. +44 (0)1480 455200 • Fax. +44 (0)1480 454126

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List of Emergency Contacts

It is very important to keep a list of emergency contacts with you at all times in case something happens to you or your pump. Before leaving the hospital, fill in the list below. If, at any time, you think your pump is not working right, call your hospital contact person, or other emergency contact, right away.

HOSPITAL

Name of Hospital _____

Name of Hospital Contact Person _____

Hospital Address _____

Hospital (Contact Person) Telephone Number _____

DOCTOR

Doctor's Name _____

Address _____

Telephone Number _____

AMBULANCE

Name _____

Address _____

Telephone number _____

AMBULANCE/ EMERGENCY SERVICES

Make sure dialing "911" works in your area before using it in an emergency. Also, consider using a land-line (non-portable) telephone for making emergency calls, unless your hospital contact person tells you otherwise. Land-line telephones may be less likely to be affected by interference, interruptions, or power outages.

Glossary

If you have questions or want more information about the terms defined below, your doctor or hospital contact person can help. You'll find these terms mentioned in this patient handbook:

A

Advisory Alarm: Advisory alarms have little or no immediate effect on circulatory support, but they do require attention and should be addressed as soon as possible. Advisory alarms are indicated by a yellow light and beeping audio tone.

B

Back Up Mode: A secondary system within the System Controller that takes over system operation and control if the primary System Controller fails or is unavailable.

Battery Clip: Device that connects the HeartMate battery and the System Controller. Two battery clips are required for battery-powered operation.

Battery Fuel Gauge (on individual batteries): Every HeartMate 12 volt nickel metal hydride (NiMH) or 14 volt lithium ion (Li-Ion) battery has a set of 5 green lights that show the battery's charge status. Pressing the battery symbol on the battery causes the lights to illuminate. Each light represents approximately 20% of available power. When a battery is charged and ready for use, all 5 lights come on. Fewer lights come on as power is depleted.

Battery Fuel Gauge (on the System Controller): During battery-powered operation, the four lights of the System Controller battery fuel gauge will show overall power capacity for both batteries. Each light represents approximately 25% of charge capacity. All four lights illuminate when charged batteries are first inserted into their clips. Fewer lights come on as power is depleted. The System Controller battery fuel gauge tells you if the batteries are running low on power and prompts you to switch to a new power source, if needed.

Battery-Powered Operation: The HeartMate II LVAS operating while connected to a pair of rechargeable, portable HeartMate batteries.

C

D

Display Module: When connected to the power module (or "PM"), the display module displays information about how the system is operating, such as the current operating mode, pump speed, flow rate, pulsatility index, power, and alarm message (if there is an

active alarm).

E

EPP: Short for Emergency Power Pack. The EPP is essentially a large battery that can be used as an emergency power source. It can provide up to 12 hours of power. It can be used, for example, during a power outage caused by a storm or severe weather. The EPP should not be used for routine power needs. It is mandatory for HeartMate II patients.

Exit Site: Location where the percutaneous lead passes out of the skin.

F

Fixed Speed Mode: Operating mode of the HeartMate II in which the pump speed is constant or "fixed". This is the standard operating mode for the HeartMate II LVAS.

G

H

Hazard Alarm: Hazard alarms occur when the pump has stopped working or is about to stop working. Hazard alarms are serious conditions that require immediate attention. They are indicated by a red light and continuous audio tone.

HeartMate Battery: HeartMate batteries are a routine power source for the HeartMate II LVAS. During battery-powered operation, the LVAS is powered by a pair of direct current (DC) batteries that are inserted into battery clips. Using batteries to power the system is called "untethered" operation; since you are not connected to the PM. Battery-powered operation allows you to be mobile and relatively active. Do NOT use batteries to power the LVAS during sleep or when there is a chance you may fall asleep, since you may not hear the System Controller's low battery alarms if you are sleeping.

HeartMate II LVAS: LVAS is short for Left Ventricular Assist System, which includes the implanted pump and percutaneous lead, as well as the external System Controller, display module, power sources (Power Module, batteries, or EPP), and accessories.

I

ICU: Short for Intensive Care Unit; where LVAS patients receive intensive care usually immediately after implant surgery.

Inflow Conduit: A small tube that connects the pump to the heart's left ventricle.

J

K

L

Low Battery Hazard Symbol: Red "battery" light (symbol) on the System Controller. It

lights when power to the System Controller is critically low.

Low Flow Hazard Symbol: Red "heart" light (symbol) on the System Controller. It lights when HeartMate II LVAD blood flow is critically low.

LPM: Short for Liters Per Minute (lpm). Blood flow through the pump is measured in LPM.

LVAD: Short for Left Ventricular Assist Device. Includes the implanted parts of the system, including the blood pump, inflow conduit and outflow graft, and percutaneous lead.

LVAS: Short for Left Ventricular Assist System. The HeartMate II LVAS includes the implanted pump and percutaneous lead, as well as the external System Controller, display module, power sources (PM, batteries, or EPP), and accessories.

N

O

Outflow Graft: Polyester graft that connects the body's main artery (aorta) to the pump's outflow elbow.

P

Perc Lock: A safety feature on the System Controller designed to lock the percutaneous lead into the System Controller socket and prevent accidental disconnection of the percutaneous lead.

Percutaneous: "Percutaneous" means "through the skin." The thin cable or lead connecting the implanted pump to the external System Controller is called a *percutaneous* lead because it passes through your skin.

Percutaneous Lead: The long lead passing through your skin that is permanently attached to the HeartMate II pump. It connects the implanted pump to the external System Controller. The percutaneous lead contains wires that carry power to the pump and control and monitor pump operation.

Percutaneous Lead Connector: Connector permanently attached to the percutaneous lead that connects the pump to the System Controller.

Polyester Velour: A synthetic biocompatible material that lets skin tissue grow into the soft covering of the percutaneous lead. This material covers the percutaneous lead inside the body at the exit site. Skin growth into the velour covering helps create a barrier that reduces the risk of percutaneous lead infections.

PM: Short for "Power Module." See "Power Module" below.

Power Module: One of two routine power sources used to power the HeartMate II LVAS. The power module (or "PM") provides power to the pump when you are connected to AC mains electrical power.

Power Saver Mode: The system automatically runs in power saver mode (pump speed will slow to a fixed speed of 8000 rpm) when battery power is low and the Red Battery

Hazard Alarm comes on.

Power Sources: Three power sources can power the HeartMate II LVAS: 1) a pair of wearable, rechargeable batteries/battery clips for battery-powered operation, 2) the power module (PM) when connected to an electrical outlet, and 3) the Emergency Power Pack (or "EPP"), which is a large battery that can power the system for up to 12 hours in the event of a power outage or emergency.

Pump Speed: Pump speed is measured in revolutions per minute (RPM). The number of RPMs reflects how fast the pump's internal rotor turns.

Pump: The implanted device connected to the left ventricle of the heart that sends blood taken from the inflow conduit through the outflow graft and into the aorta, which sends the blood to the rest of the body. The pump contains titanium stators, a rotor, a blood tube, and ceramic bearings. The motor capsule that surrounds the rotor is powered through the percutaneous lead.

Q

R

S

Self Test: A routine system check performed daily by the patient to confirm that the System Controller's audio and visual alarms are working properly.

Silence Alarm Button: A button used to temporarily mute or silence System Controller alarms so users can respond to alarm conditions without audio distraction. Pressing and holding this button will also display how much battery power is available (when connected to battery power).

System Controller Battery Module Symbol: A round yellow symbol on the System Controller that lights when the System Controller's battery module needs to be replaced.

System Controller Battery Module: A small, replaceable battery cell that powers the audio alarms on the System Controller when both power leads are disconnected from the power source (batteries, PM or EPP) at the same time. Note: The System Controller battery module only powers the System Controller audio alarms. It does NOT provide back up power to the implanted pump.

System Controller Power Leads: Two power leads (one with a black connector and one with a white connector) connect the System Controller to its power source (either batteries, PM, or EPP). Both leads provide equal power. However, the white lead contains a data link cable that sends information to the power module and/or display module during tethered operation (i.e., when using the PM for power).

System Controller: The small computer that controls and monitors system function. It connects the implanted pump to the external power sources and may be worn at the waist on a belt or in a carrying case around the waist.

T

Test Select Button: A button found on the System Controller. Pressing and holding this button starts the System Controller self-test which should be performed daily to check System Controller lights and audio alarm tones.

Tethered Operation: Refers to using the HeartMate II LVAS while connected to an electrical outlet via the PM.

U

UBC: Short for "Universal Battery Charger." See "Universal Battery Charger" below.

Universal Battery Charger: The HeartMate Universal Battery Charger (UBC) charges and tests HeartMate 12 volt NiMH batteries and HeartMate 14 volt Li-Ion batteries that are used to power the HeartMate II LVAS during "tethered" operation.

User Interface Panel: Set of visual indicators (symbols that light) and buttons located on the front of the System Controller.

V

Visual Indicator Lamp: Yellow and red lights on the System Controller and the PM that turn on during advisory or hazard conditions.

W

X

Y

Z

111

Figure A Implanted and Worn Components of the HeartMate II LVAS During Battery-Power Operation

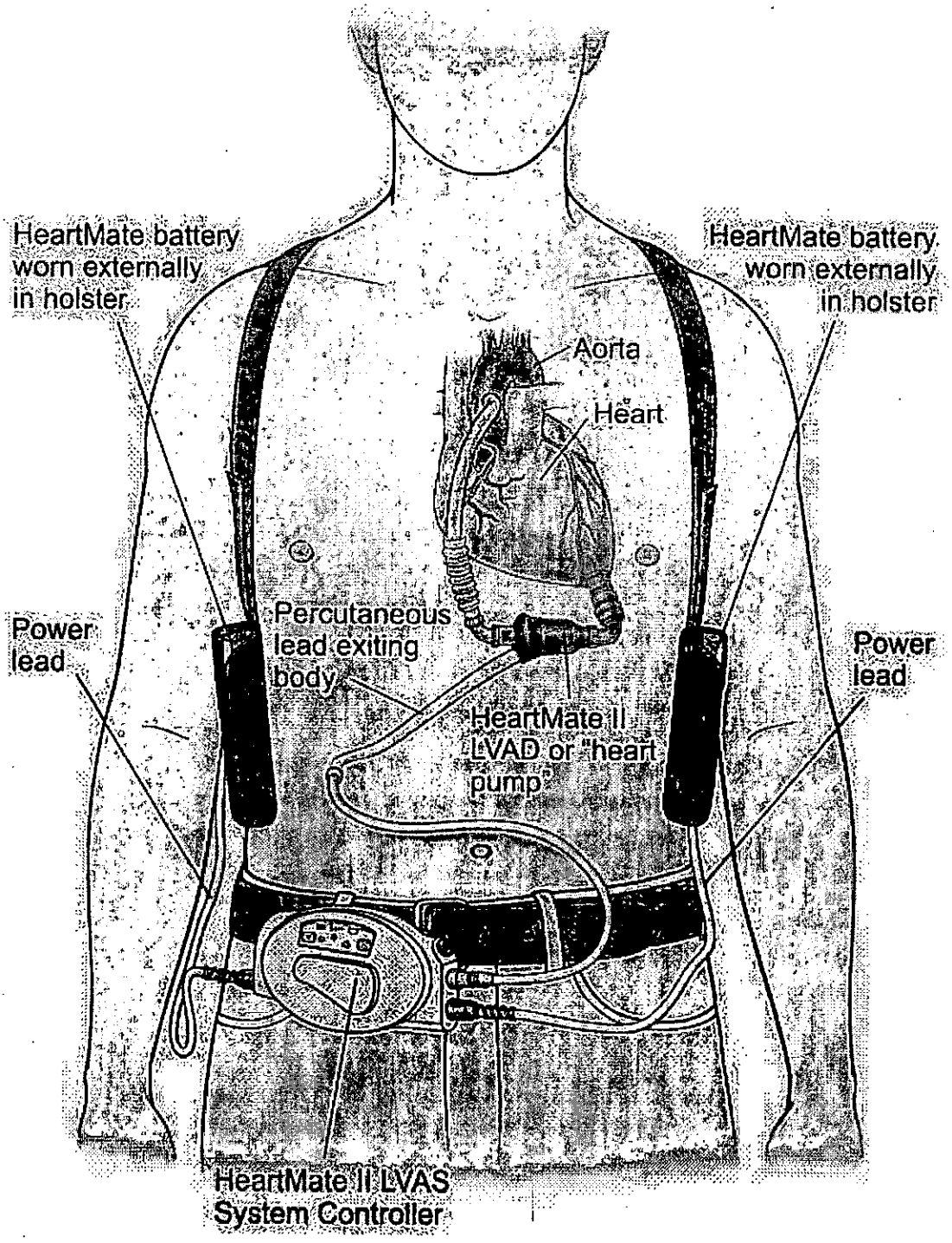
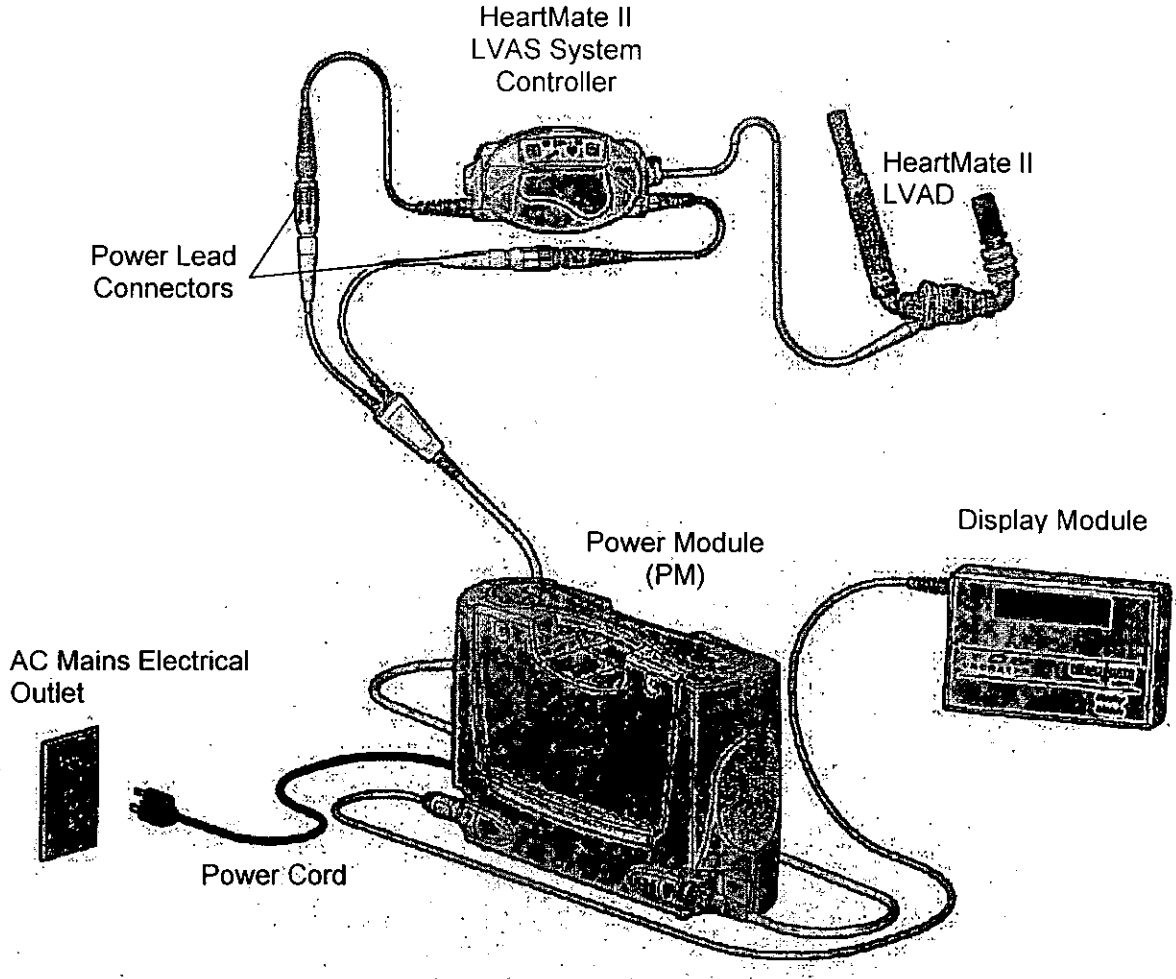


Figure B HeartMate LVAS during "Tethered Operation" Connected to Power Module (PM)



Important Warnings

- Understanding the operating and the safety aspects of HeartMate products is essential for safe and successful use. All users (including clinicians, patients, and caregivers) must be trained on system operation and safety aspects before use.
- A thorough understanding of the technical principles, clinical applications, and risks of left ventricular support is necessary before using this product. Read this entire *HeartMate II LVAS Patient Handbook* before use.
- Before using any HeartMate power accessories (Power Module, and Universal Battery Charger, or batteries), all users (including clinicians, patients and caregivers) must be trained on their use. Manuals for HeartMate power accessories include:
  - *HeartMate 12 Volt NiMH Battery Instructions for Use (IFU)* (document # 103769)
  - *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770)
  - *HeartMate Universal Battery Charger IFU* (document # 103771)
  - *HeartMate Power Module IFU* (document # 103772)
- Certain components of the HeartMate II LVAS are NOT compatible with other HeartMate systems (such as the XVE LVAS). Use only HeartMate II system components while implanted with the HeartMate II LVAS.
- HeartMate 14 volt lithium ion (Li-Ion) batteries are for use exclusively with the HeartMate II LVAS. They are NOT compatible with the XVE system and cannot power the XVE LVAS. However, HeartMate 12 volt nickel metal hydride (NiMH) batteries can power both the HeartMate XVE LVAS and the HeartMate II LVAS. Make sure you are using the correct batteries before relying on them for power. Using incompatible batteries will result in pump failure. See the *HeartMate 12 Volt NiMH Battery IFU* (document # 103769) *or* the *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770) for detailed information on the HeartMate batteries used to power your system.
- Use batteries in matching pairs (two 12 volt NiMH batteries or two 14 volt Li-Ion batteries).

Important Warnings continued

- Use only compatible battery clips to connect with HeartMate batteries. Use 12 volt battery clips with 12 volt NiMH batteries, and 14 volt battery clips with 14 volt Li-Ion batteries. Other battery clips will not transfer electrical power to the HeartMate II LVAS. See the *HeartMate 12 Volt Battery IFU* (document # 103769) and the *HeartMate 14 Volt NiMH Battery IFU* (document # 103770) for detailed warnings, precautions, and instructions.
- ALWAYS connect to AC mains electrical power through the Power Module (PM) for sleep or when anticipating sleep. Use battery power only when you are awake and able to respond to system alerts and alarms.
- The HeartMate Power Module (PM) and Universal Battery Charger (UBC) generate, and can radiate radio frequency energy. If not installed and used according to instructions, it may cause harmful interference with other devices in the area. There is no guarantee that interference will not occur in a particular installation/use of the PM and/or UBC. Interference can be determined by unplugging/plugging in the PM and/or turning off/on the UBC and seeing the affect on devices in the area. If interference is detected while the patient is connected to the PM, attempt to correct it by *FIRST* SWITCHING TO BATTERY POWER and then:
  - Re-orienting or moving the affected device(s).
  - Increasing the distance between the PM and/or UBC and the affected device(s).
  - Connecting the affected device(s) to an electrical outlet different from the outlet used to power the PM and/or the UBC.
  - Consulting with your hospital contact person for advice and assistance. See the *HeartMate Power Module IFU* (document # 103772).
- If traveling internationally, you will need a Thoratec power cord set that is compatible with the local voltage and that meets applicable national plug, rated voltage, rated current, and safety agency marks and specifications for both the PM and UBC. Contact your VAD Coordinator or hospital contact person for a Thoratec power cord set, if needed.

Important Warnings continued

- Do NOT swim or take tub baths while implanted with the pump. You may be allowed to shower after enough healing has occurred. Your doctor will tell you if you can shower. Do NOT shower without your doctor's permission.
- If approved for showering, always use the HeartMate GoGear shower bag to protect external parts of the system from water or moisture. See the *HeartMate GoGear Shower Bag IFU* (document #104614).
- Never put external system components or power accessories (such as the System Controller, PM, batteries, battery cables, or battery clips) into water or liquid.
- Keep the PM and the UBC away from water or moisture. If the PM touches water, rain/snow, shower spray, or wet surfaces, you may get a serious electric shock, or the PM may fail to operate properly. If the UBC touches water, rain/snow, shower spray, or wet surfaces, it may not be able to charge the batteries or you may get a serious electric shock.
- PM connectors should be kept clean and dry. Do not expose connectors to water, moisture, rain/snow, dirt, etc. when making or breaking connections.
- Do NOT use the PM or UBC near a flammable anesthetic mixture (with air or with oxygen or nitrous oxide), or an explosion may occur.
- Check the System Controller Perc Lock often to make sure it is in the locked position. The Perc Lock helps keep the percutaneous lead from accidentally disconnecting from the System Controller. If the percutaneous lead disconnects, your pump will stop.
- The pump will stop if the System Controller is disconnected from the percutaneous lead going through your skin. If this happens, reconnect the lead as quickly as possible to restart the pump.
- When exchanging batteries, never disconnect both batteries at the same time or your pump will stop (see *Exchanging Used Batteries With Charged Batteries*, page 61).
- At least one System Controller power lead must be connected to a power source (batteries, PM, or EPP) at all times. If both System Controller power leads are disconnected at the same time, your pump will stop.

Important Warnings continued

- Losing power will make the pump stop. Power must be restored right away to restart the pump.
- Plug the PM only into properly grounded (3-prong) outlets dedicated to PM use. Do NOT use an adapter (cheater plug) for ungrounded outlets or multiple portable socket outlets (power strips) or you may get a serious electric shock or the pump may stop.
- Do NOT connect the PM or the UBC to an outlet controlled by a wall switch or the device may not work.
- The PM, like any piece of electrically-powered life-sustaining equipment should remain plugged into a properly-grounded (3-prong) AC mains electrical outlet that is dedicated to its use, except during transport or service/maintenance. The PM's internal battery (that provides limited backup power to the LVAD in the event of AC mains power failure) remains charged as long as the PM is connected to AC or DC power.
- The PM contains an internal battery. When new, the internal battery provides approximately 30 minutes of emergency backup power for the HeartMate II LVAS in the event of AC mains interruption/failure. If the PM is used in cold conditions (32-59°F, 0-19°C), the backup battery runtime may be reduced to a minimum of 20 minutes.
- The PM is shipped with its internal battery disconnected. The internal battery must be connected before using the PM. If the internal battery is not connected, the backup power source will not work. The backup battery should be connected by a properly trained person. See the *HeartMate Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on the PM's internal battery.
- Make sure the PM's internal battery is connected before using the PM for the first time. Also, make sure it is connected any time after the PM is shipped for service and maintenance.

Important Warnings continued

- Transfer from the PM to batteries during AC mains power failure. The PM has an internal backup battery that will power the pump while you transfer to batteries. The internal backup battery should not be used as a backup power source for the system during AC mains power failure. The Display Module or System Monitor will not work if connected to the PM during a power failure. In addition, the PM's battery charge status indicators will not work during AC mains power failure.
- Your primary source of power during mobile operation (i.e., while not connected to AC mains electrical power) should be the HeartMate batteries. The use of DC power from a car's DC power adapter should be temporary and for convenience only. DC power can vary from vehicle to vehicle. If a car's DC power is inadequate to power the LVAS, the PM will alarm or switch to the internal back-up battery. If this occurs, switch to batteries and discontinue the use of automobile DC power.
- The use of DC power from an automobile power outlet is intended for convenience while traveling by car. DC power from an automobile power outlet is NOT meant to be a primary power source; its use should be temporary only. While traveling by car and using DC power, you should have at least one set of charged HeartMate batteries and cables in close proximity so you can promptly switch to battery power if needed. See the *HeartMate Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on using the PM with automobile DC power.
- The automobile engine must be ON and RUNNING BEFORE connecting the PM to its DC power outlet.
- If a "jump start" is needed to start the car that is being used for automobile DC power, first switch to different power source and then unplug the PM from the DC power outlet before the "jump" to prevent damage to the PM. See the *HeartMate Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions.
- Have the car's DC power checked by a trained technician or mechanic to make sure that it can provide adequate, reliable power before using it to power your LVAS. Do NOT use automobile DC power if it is inadequate or unreliable.

Important Warnings continued

- Do NOT touch television (TV) or computer screens while implanted with the pump. TV and computer screens have strong static electricity. A strong electric shock can damage electrical parts of the system and make the pump stop.
- Do NOT vacuum or engage in activities that may create static electricity. A strong electric shock can damage the electrical parts of the pump and make the pump stop.
- Do not become pregnant while you have the pump. If you are a woman of childbearing age, use birth control if you are sexually active. Blood thinners (which most LVAD patients receive) have been associated with birth defects. In addition, a growing fetus may dislodge the pump, which could cause catastrophic bleeding and death. If you do become pregnant, immediately tell your doctor and hospital contact person.
- Never have an MRI (magnetic resonance imaging) done while you have the pump. An MRI may injure you or make the pump stop.
- In case of an emergency, keep a back-up System Controller, spare charged batteries, battery cables, and compatible battery clips **with you at all times**.

Important Precautions

- When connecting leads, do not force them together without first lining up the connectors. Forcing together misaligned connectors may damage them.
- Never use tools to tighten connectors. Hand tighten only. Using tools may damage connectors.
- **HeartMate 14 volt Li-Ion batteries must be charged at least once by the end of the month marked on the label placed on battery packaging** (box and protective bag). If a 14 volt Li-Ion battery is not charged by this date, battery operating time may be affected, which can cause the pump to stop. Do not use a HeartMate 14 volt Li-Ion battery if it has not been charged by the date indicated. It has expired. See the *HeartMate 14 Volt Battery IFU* (document # 103770).
- Dispose of expired or defective HeartMate batteries according to local, state, and federal regulations.
- Do NOT use expired or damaged batteries. Using expired or damaged batteries may cut operating time or cause the pump to suddenly stop.
- As batteries get older, they will power the system for shorter periods of time. If a pair of batteries does not give at least four hours of support, remove both batteries from service.
- If stored and used within recommended guidelines, HeartMate batteries should be usable for approximately 360 use/charge cycles *or* for 36 months from the date of manufacture, whichever comes first. After 360 cycles/36 months, battery performance cannot be guaranteed and batteries should be replaced. See the manual that came with your HeartMate batteries for specific storage and use guidelines.

Important Precautions continued

- To prevent battery damage:
  - Do NOT drop batteries or hit them against hard objects or each other.
  - Do NOT use batteries in temperatures that are below 32°F (0°C) or above 104°F (40°C).
  - Do NOT leave or store batteries in extremely hot or cold areas (car trunks, etc.) or battery life will be shortened.
  - Do NOT directly connect battery contacts to each other (short circuiting).
- Do not store batteries together with keys, coins, or other loose metallic objects. Metal objects touching the exposed battery contacts may cause an accidental short or connection between the battery contacts, which can result in battery overheating that may burn you or damage the batteries.
- Use only the HeartMate UBC to charge HeartMate 12 volt NiMH batteries or HeartMate 14 volt Li-Ion batteries. Other battery chargers may damage HeartMate batteries. See the *HeartMate Universal Battery Charger IFU* (document # 103771) for detailed warnings, precautions, and instructions on charging HeartMate batteries.
- The UBC requires planned maintenance at least once every 12 months for the best possible operation. Planned maintenance includes (but is not limited to) a functional check of the device and cleaning/inspecting all internal connections. Talk with your VAD Coordinator or hospital contact about scheduling this service, if needed.
- The HeartMate UBC cannot test or charge the black sealed lead acid (SLA) HeartMate batteries originally used with the HeartMate Power Base Unit (PBU).
- Make sure the UBC is plugged in and turned on ("I") before placing batteries into the pockets for charging.
- Before inserting a HeartMate NiMH or Li-Ion battery into the UBC for charging, inspect the battery for signs of damage. Do not use a battery that appears damaged. Call your hospital contact person for a replacement, if needed.

Important Precautions continued

- Dirty battery terminals may prevent proper battery charging, which can affect battery performance. The metal contacts on the batteries and inside the battery clips should be cleaned at least once a week with a lint-free cloth or cotton swab that has been moistened (not dripping) with rubbing alcohol. Let the alcohol dry before using the batteries or clips, or before placing the batteries into the UBC. See *Cleaning Batteries and Battery Clips*, page 64.
- After approximately 70 uses, HeartMate NiMH or Li-Ion batteries may need to be calibrated. The UBC will tell you when an inserted battery needs to be calibrated. Calibration can take up to 12 hours, and only one battery can be calibrated at a time. Calibrate a battery as soon as possible after being told to do so to prevent a backlog of uncalibrated batteries. See the HeartMate *Universal Battery Charger IFU* (document # 103771) for detailed warnings, precautions, and instructions on battery calibration.
- Leave a calibrating battery in the UBC for the entire calibration cycle. Removing a battery before it is fully calibrated, may result in a fully-depleted battery. See the HeartMate *Universal Battery Charger IFU* (document # 103771) for detailed warnings, precautions, and instructions on battery calibration.
- Do NOT play contact sports or engage in jumping activities while implanted with the pump. Contact sports or jumping can cause bleeding or damage the pump.
- The HeartMate uses sounds and lights to tell you how the system is working. If you have trouble hearing or seeing, you might need extra help to hear or see the sounds and lights. You might be at higher risk of injury if you have trouble hearing or seeing. Talk with your hospital contact person if you have questions or concerns about this.
- To prevent damage to the Emergency Power Pack (EPP):
  - Do NOT leave or store the EPP in hot or cold areas (car trunks, etc.), or EPP life will be shortened.
  - Do NOT use EPP after its expiration date.

Important Precautions continued

- Do NOT store or use the EPP in temperatures below 32° F (0°C) or above 122°F (50°C), or the EPP may suddenly stop working. If your EPP stays below room temperature (68°F–72°F, 20°C–23°C) during use, it will run the pump for less than 12 hours. In low temperatures (32°F – 5°F, 0°C – -15°C), run time may cut by 50%.

- Dispose of an expired or used EPP according to local, state, and federal regulations. Do NOT burn.
- Do NOT try to fix any of your LVAS equipment yourself. If equipment needs service, call your hospital contact person.
- Do NOT drop the System Controller or subject it to extreme physical shock.
- Do NOT pull on or move the percutaneous lead going through your skin. Pulling on or moving the lead can keep the exit site from healing. Pulling on or moving the lead can also increase the risk of getting a serious infection.
- Be extremely careful with your percutaneous lead. Check your lead often to make sure it does not get twisted. If your percutaneous lead does become twisted, carefully turn the System Controller to unravel the lead. Turn until the lead is no longer twisted.
- Do NOT kink or bend the percutaneous lead. Check your lead often to make sure it is free of kinks or sharp bends. A kink or sharp bend in the percutaneous lead may damage the wires inside.
- Call your doctor if you notice a change in how your pump works, sounds, or feels.
- Wear the HeartMate Stabilization Belt (or other abdominal binder) at all times to keep your percutaneous lead in place.

Introduction

Why Should You Read this Handbook?

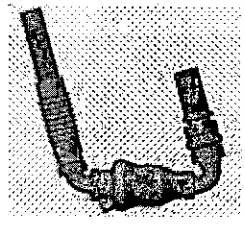
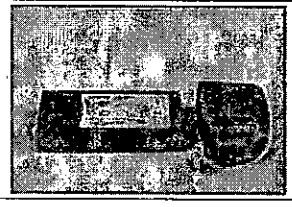
This manual will teach you about your new HeartMate II heart pump. Read it to learn how the pump works and how to keep safe while living with the pump outside the hospital. This manual is also important because it explains what to do in an emergency. If you have any questions after reading this handbook, ask your doctor or hospital contact person.

Note: To reduce the risk of complications, you should closely follow the guidelines in this handbook.

The table below lists the major parts of the pump system and gives a short description for each. Each part is explained in more detail later in this handbook.

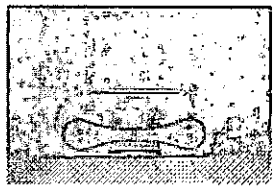
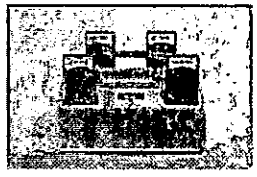
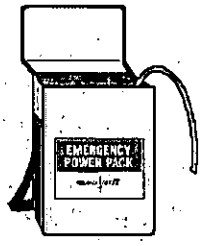
System Components

Table 1 HeartMate II LVAS System Components

Pump		The pump moves blood from your heart to other parts of your body. The pump is implanted below your heart. A percutaneous lead, which is attached to the pump, passes through the skin of your abdomen. The lead connects the implanted pump to the external System Controller.
System Controller		The System Controller is a small computer. It controls and continually checks system operation. It uses lights and sounds to tell you how the system is working.
Batteries and Battery Clips		HeartMate batteries are a routine power source. They are used for powering the pump during mobile operation. Batteries are used in pairs. Each battery is inserted into a battery clip. The clips connect to the System Controller. They transfer battery power to the system.

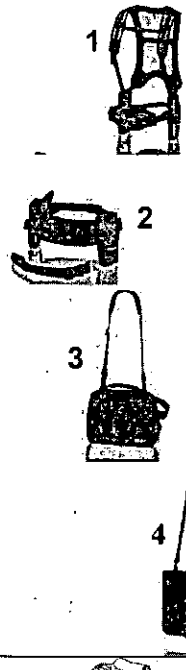
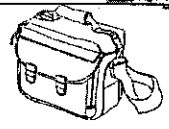
System Components continued

Table 1 (continued)

Power Module (PM)		The Power Module (PM) is the other routine power source. When the PM is plugged into an electrical outlet, it provides AC mains electrical power to the system. See the *HeartMate Power Module IFU* (document # 103772).
PM Patient Cable		The PM patient cable connects the PM to the System Controller. Connections are made between white-to-white and black-to-black connectors.
Universal Battery Charger (UBC)		The Universal Battery Charger (UBC) charges and tests HeartMate 12 volt NiMH and 14 volt Li-Ion batteries. See the *HeartMate Universal Battery Charger IFU* (document # 103771).
Emergency Power Pack (EPP)		The EPP is an emergency power source. It can provide up to 12 hours of power. For example, during a power outage caused by a storm or severe weather. The EPP is mandatory for HeartMate II patients. **See page 90 for instructions on using the EPP.**
Display Module		When connected to the PM, the Display Module shows information about how the pump is working, such as: pump speed, flow rate, pulsatility index (PI), and power. The pump's operating mode and other operating information also appears on the screen. Using the Display Module is optional.

System Components continued

Table 1 (continued)

GoGear™ Wearable Accessories		GoGear wearable accessories hold the System Controller and batteries in a variety of options: **1**) the **Holster Vest** holds your batteries on both sides of your body. The optional waist belt helps secure the system controller. **2**) The **Modular Belt** holds the system controller and batteries around your waist. **3**) The **Consolidated Bag** holds your System Controller and batteries together in the bag and is worn across the body. **4**) The **Shower Bag** keeps the system controller and batteries dry when you shower and is worn across the body.
Travel Case		For carrying emergency or back-up HeartMate equipment, such as spare batteries and a back up System Controller.

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How Does It Work?

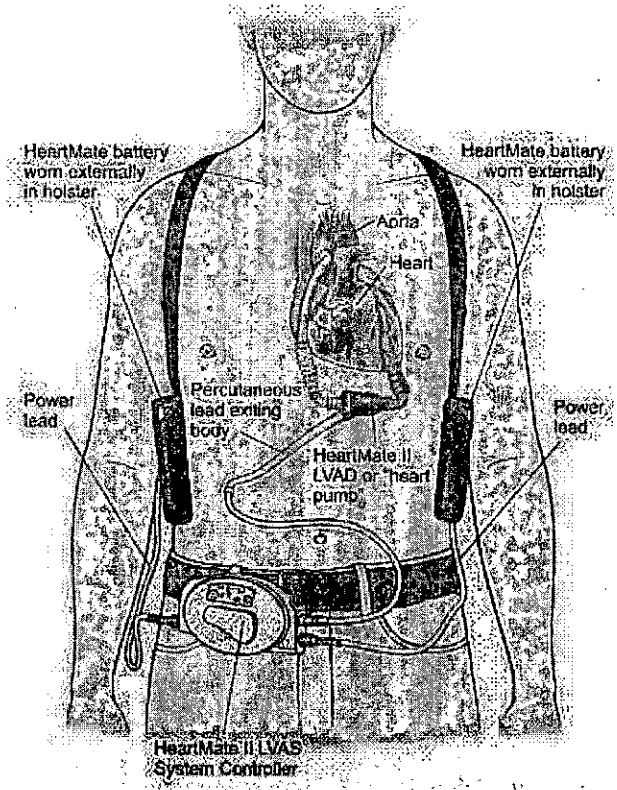
Your Heart Pump

Your heart pump is called the HeartMate II **L**eft **V**entricular **A**ssist **D**evice (LVAD). The LVAD helps your heart pump blood through your body. A small electric motor inside the LVAD drives the pump. The LVAD is placed (implanted) below your heart. It is attached to your heart and the aorta (the large blood vessel that carries blood from your heart to the rest of your body) (**Figure 1**). Blood from your heart flows into the LVAD. Blood is then pumped into the aorta; and, from there, to the rest of your body.

Your heart pump helps your heart by taking over the function of the diseased left ventricle (your heart's main pumping chamber). The electric motor drives a small rotor (similar to a propeller), which pushes blood into the aorta and out to the body. Your heart pump is designed to restore blood circulation to the body and its primary organs. You may feel the pump working. This is normal.

Your Heart Pump continued

Figure 1

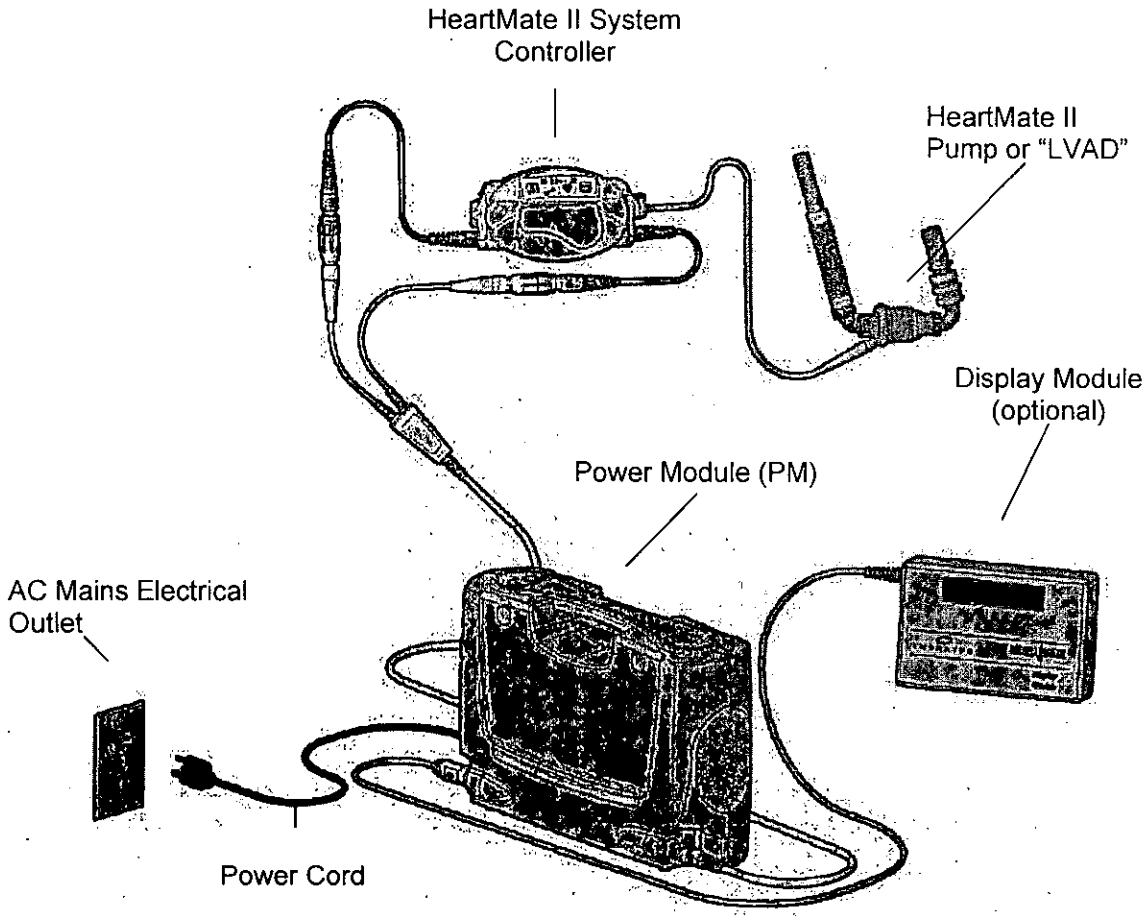


As shown in **Figure 1**, a thin cable passes through your skin. It is called a percutaneous lead. "Percutaneous" means "through the skin." The outside of the lead is covered with a special material that lets skin cells grow into it. This helps the exit site heal. A well-healed exit site can lower the risk of infection. You will need to keep the exit site very clean and dry. A clean, dry exit site also helps lower infection risk (see *Caring for the Exit Site,* page 108).

Power leads connect the System Controller to a power source (either batteries, PM or EPP). When the System Controller is connected to battery power, you'll wear system components using a GoGear wearable accessory, such as the holster vest (**Figure 1**), or the bag or belt option that is worn around the waist or across your body. The System Controller can also be powered by AC mains electrical power when connected to the PM that is plugged into an electrical outlet (**Figure 2**).

Your Heart Pump continued

Figure 2

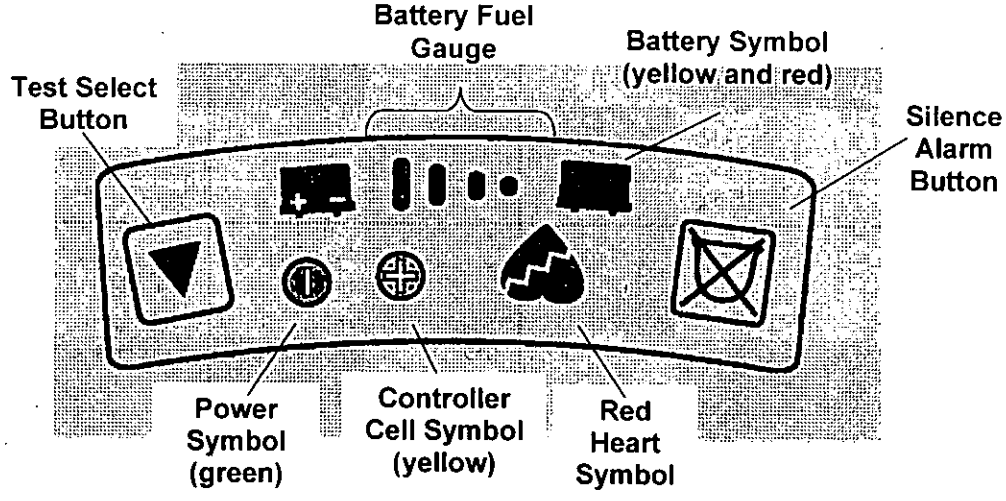


The System Controller

The System Controller is a small computer. It makes sure your pump is working properly. The System Controller is connected to both the pump and a power supply (batteries, PM, or EPP). It is usually worn on the belt or waistband.

The System Controller warns you if there is a problem with your pump or its power supply. The Controller's warning lights, buttons, and battery fuel gauge are on the top of the device (**Figure 3**). The Controller's lights, buttons, and the battery fuel gauge are described on the following pages.

Figure 3



CAUTION !

The HeartMate II LVAS uses sounds and lights to tell you how the system is working. If you have trouble hearing or seeing, you might need extra help to hear or see the sounds and lights. You might be at higher risk of injury if you have trouble hearing or seeing. Talk with your hospital contact person if you have questions or concerns about this.

The System Controller continued

Table 2 System Controller Warning Lights and Sounds

WARNING LIGHTS & SOUNDS	MEANING	WHAT YOU SHOULD DO
Red Heart *CONTINUOUS AUDIO TONE* 	Pump flow is less than 2.5 lpm, pump has stopped, perc lead is disconnected, or pump is not working properly.	1 Make sure System Controller is connected to the pump. 2 Make sure System Controller is connected to a power source (batteries, PM, or EPP). 3 If alarm continues, immediately call for emergency help (dial 911 if available), then call your hospital contact person.
CONTINUOUS AUDIO TONE, but no warning light and no green power symbol.	System Controller is not receiving power.	1 Make sure System Controller is connected to a power source (batteries, PM, or EPP). 2 If connected and alarm continues, switch to a different power source. 3 If alarm continues after switching power source, replace the System Controller (see page 27 for instructions).
Red Battery *CONTINUOUS AUDIO TONE* 	Less than 5 minutes of battery power remain, voltage is too low, or the System Controller is not getting enough power from the PM.	Immediately replace depleted batteries with a new, charged pair. Change batteries one at a time. If charged batteries are not available, switch to PM or EPP. **WARNING! Do NOT remove power from both power leads at the same time, or the pump will stop.** **Note**: Pump speed will gradually decrease to save power (i.e., Power Saver Mode) until the condition is resolved and the alarm clears (see *Power Saver Mode*, page 64).
Yellow Battery *1 beep every 4 seconds* 	Less than 15 minutes of battery power remain, voltage is too low, or System Controller is not getting enough power from the PM.	Immediately replace depleted batteries with a new, charged pair. Change batteries **one at a time**. If charged batteries are not available, switch to PM or EPP. **WARNING! Do NOT remove power from both power leads at the same time, or the pump will stop.**

continued

The System Controller continued

Table 2 (continued)

WARNING LIGHTS & SOUNDS	MEANING	WHAT YOU SHOULD DO
Beeping AUDIO TONE (repeating cycle of 1 beep per second for 2 seconds, followed by 2 seconds of silence), but NO warning light.	System Controller is operating in back-up mode.	1 Replace the System Controller (see page 27). 2 Call your hospital contact person. 3 Obtain a new, backup System Controller from your hospital contact person.
Controller Cell *Yellow symbol; 1 beep every 4 seconds* 	The battery module that powers the System Controller audible alarm is low on power.	Change the System Controllers battery module (see page 25).
Rapidly Flashing Power Symbol  *and* **Four (4) Flashing Green Lights (on Battery Fuel Gauge)** *flash once per second*  *1 beep every second*	One of the power leads is disconnected or damaged.	1 Reconnect or tighten disconnected/loose power lead. 2 If alarm continues, check System Controller power lead and PM power lead for damage. 3 If System Controller power lead or PM power lead is damaged, replace the System Controller (see page 27) and/or replace the PM cable. 4 Obtain a new, backup System Controller from your hospital contact person.
1 beep every 4 seconds *No Warning Light*	Pump is operating below low speed limit.	Call your hospital contact person.

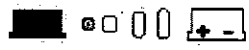
The System Controller continued

Table 3 System Controller Buttons

SWITCH	PURPOSE	HOW TO USE
Test Select Button 	Starts the System Controller Self Test.	Push and hold for three seconds to start Self Test. See "System Controller Self-Test" on page 22. **Note**: Pressing this button will have no effect when an alarm is active. A self-test can be done only when there are no active alarms.
Silence Alarm Button 	Allows you to: ▪ Silence Advisory Alarms for 4 hours. ▪ Silence RED Hazard Alarms for two minutes. ▪ Silence the Power Cable Disconnect Alarm for two minutes if one of the power leads is disconnected or damaged. ▪ Silence both the System Controller and the PM if you are attached to the PM when the System Controller alarms.	Firmly press and hold for a count of two, then let go. **Note**: Do not silence an alarm without first finding out why it is occurring. Silencing the alarm does not fix the problem. Be sure to have a plan for fixing the problem before silencing any alarm.
Silence Alarm Button 	Lets you check how much battery power remains (see "Battery Fuel Gauge" next page).	Press and hold Silence Alarm Button for a count of two.

The System Controller continued

Table 4 Battery Fuel Gauge

BATTERY FUEL GAUGE LIGHTS	MEANING	WHAT YOU SHOULD DO
Four (4) Green Lights 	Between 75% – 100% of battery power available.	No Action Needed.
Three (3) Green Lights 	Between 50% – 75% of battery power remains.	No Action Needed.
Two (2) Green Lights 	Between 25% – 50% of battery power remains.	No Action Needed.
One (1) Green Light 	Less than 25% of battery power remains.	Replace used batteries with charged ones, or switch to PM.
Four (4) Flashing Green Lights **(on Battery Fuel Gauge)** *flash once per second*  *and* **Rapidly Flashing Power Symbol**  *1 beep every second*	One of the power leads is disconnected or damaged.	Check for loose or damaged power leads. If on PM power, make sure power lead is not disconnected or damaged.

The System Controller continued

System Controller Self-Test

At least once a day you should test the System Controller to make sure that it is working properly. The self-test takes about 10 seconds. During the self-test your pump will continue to run. For your comfort, we recommend that you sit down during the test. Place the System Controller where you can easily push the buttons and see the lights during the test.

Performing a System Controller Self-Test

1 To start the self-test, press and hold the Test Select Button for three seconds. *After three seconds, the Red Heart , Red and Yellow Battery , Yellow Controller Cell Symbol , and Fuel Gauge lights will come on, along with a CONTINUOUS AUDIO TONE.*

Note: Pressing the Test Select Button will have no effect when an alarm is active. A self-test can be performed only when there are no active alarms.

2 Look closely at the System Controller display panel. Make sure that all of the lights are on and the alarm is making a CONTINUOUS AUDIO TONE. *If there is a problem with the audio alarm, it will beep once every two seconds instead of a continuous or steady tone.*

3 Release the Test Select Button.
All the lights should remain on and the alarm should sound a CONTINUOUS AUDIO TONE for an additional five seconds.

4 If all the alarms and lights come on as described above and then turn off five seconds after releasing the button, the System Controller has passed the self-test.

Note: If there are any problems or if your System Controller fails the test, call your hospital contact person.

The System Controller continued

System Controller Perc Lock

The System Controller's Perc Lock keeps the percutaneous lead from accidentally disconnecting from the Controller (if you accidentally hit the release tab, for example). If the lead disconnects, your pump will stop. Therefore, it is important to have the Perc Lock in the locked position at all times.

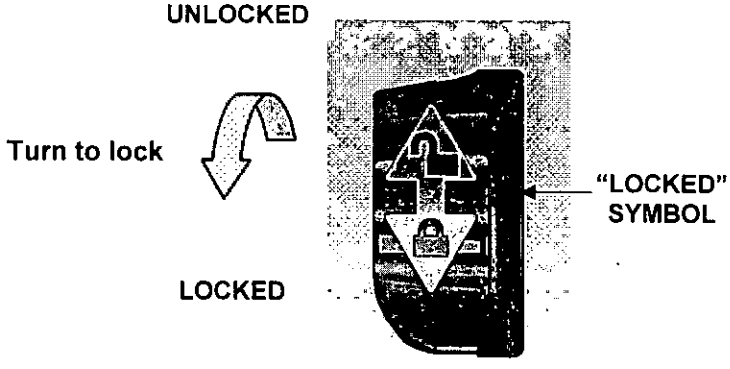
How to Use and Check the Perc Lock

Follow these steps to make sure the Perc Lock is properly locked:

1 While sitting down, turn (rotate) the Perc Lock on the System Control towards the "locked" symbol 🔒 (**Figure 4**).

Note: Keep turning until the Perc Lock "clicks" into place.

Figure 4



2 If the Perc Lock does not rotate, make sure the connector is fully inserted into the System Controller socket.

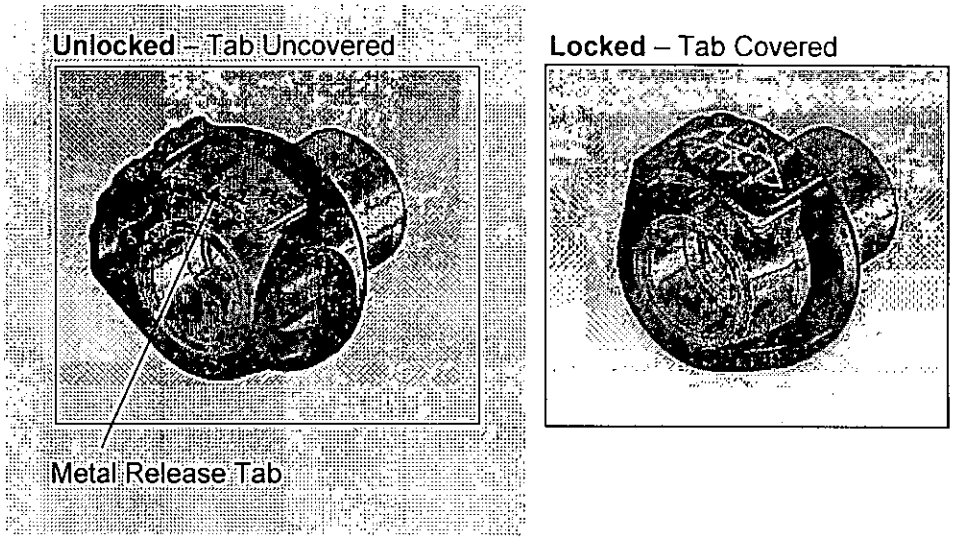
Note: The Perc Lock will not rotate unless the connector is fully inserted.

3 After it clicks into place, inspect the Perc Lock to make sure it is fully locked.

Note: If fully locked, the Perc Lock will cover the metal release tab (**Figure 5**).

The System Controller continued

Figure 5



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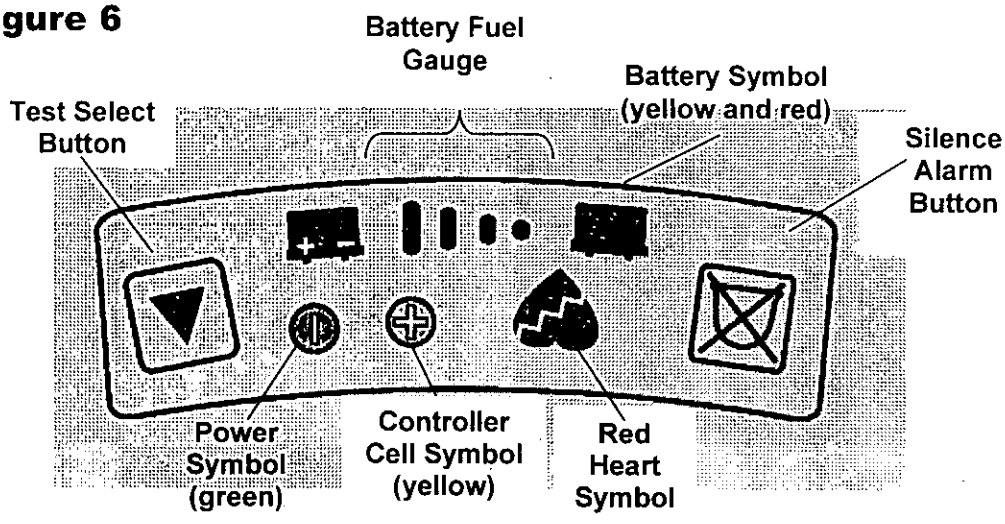
The System Controller continued

Changing the System Controller Battery Module

A small battery module powers the System Controller (not the pump). When the battery module is running low, the yellow battery module symbol ⊕ (on top of the System Controller) comes on (**Figure 6**).

Note: The System Controller battery module only powers the System Controller audio tone. It does NOT power the pump and will not provide back-up power to the pump in the event of a power failure.

Figure 6



Follow these steps to change the System Controller battery module:

1 Obtain a new System Controller battery module.

2 Examine the new battery module. Make sure there is white tape around the sides of the battery module and an orange O-ring around the bottom. If the white tape or orange O-ring is missing, do NOT use the battery module. Get a new one.

3 Unscrew (counterclockwise) the old battery module from the side of the System Controller. Throw away the old battery module.

Note: If the old battery module is hard to remove, use a flat object (like a coin) in the slot for leverage.

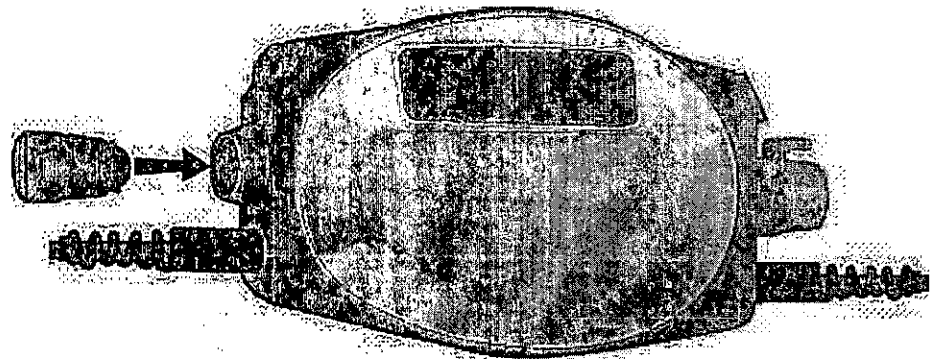
Changing the System Controller Battery Module continued

4 Insert the new battery module into the System Controller (**Figure 7**).

5 Turn the new battery module clockwise until you can no longer see the orange O-ring. You can use a flat object (like a coin) to tighten the battery module. **But do NOT over tighten it**.

6 Once the battery module is properly inserted, the yellow battery module symbol ⊕ will turn off.

Figure 7



Replacing System Controllers

If your pump stops, the System Controller will alarm. The Red Heart Symbol will light and a CONTINUOUS AUDIO TONE will sound

If your pump stops, switching to the back up System Controller might restart it. But, BEFORE trying to replace System Controllers, make sure you fully understand how to do it. Have someone help, if possible. Help could make it faster and easier to replace the Controller.

Note: When pump power is interrupted (e.g., perc lead disconnected or both batteries disconnected at the same time), the pump will stop. When power is restored, the System Controller will automatically restart the pump at the previously-set speed.

Follow these steps to replace the current System Controller:

1 Place the *replacement* System Controller within easy reach, along with the batteries/battery clips or PM cable.

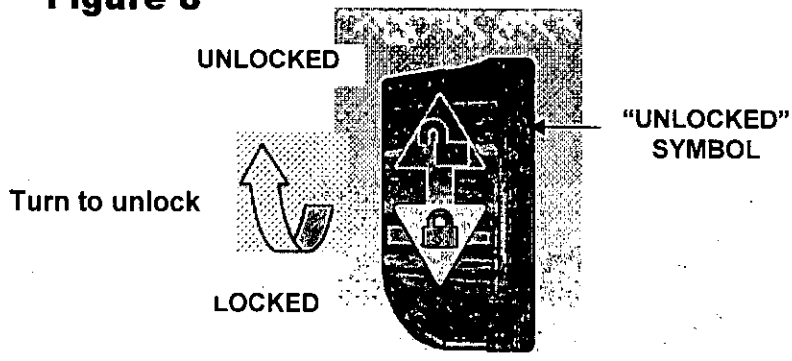
2 Sit or lie down.

3 Rotate the perc lock on the new, *replacement* Controller in the direction of the "unlocked" icon until the perc lock clicks into the fully-unlocked position.

4 Repeat Step 3 for the *original* Controller until the perc lock clicks into the fully-unlocked position.

Note: Keep turning until the Perc Lock clicks into the unlocked position and the metal release tab is showing (**Figure 8**).

Figure 8



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Replacing System Controllers continued

5 Attach the power leads on the new, *replacement* Controller to the PM cable or to the battery clips, depending on the power source being used.

6 If using battery power, place charged batteries into the battery clips *after* attaching the power leads.

7 Press the Silence Alarm ⊠ Button on the new, *replacement* Controller to silence its Red Heart ♥ Alarm for two minutes.

8 Disconnect the perc lead from the *original* Controller by pressing the metal release tab on the connector socket. *The pump will stop and an alarm will sound until power is removed from the original Controller.*

Note: Getting the new Controller connected and the pump restarted is the first priority. Ignore the alarm for the old Controller for now. You can disconnect the old Controller and stop its alarm once the new Controller is connected

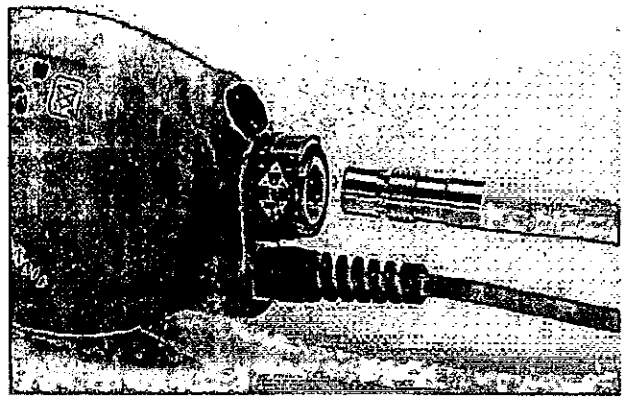
9 Connect the new, *replacement* Controller:

a Line up the mark on the perc lead connector with the mark on the metal tab of the new Controller.

b Fully insert the connector into the socket of the new Controller (**Figure 9**). *The pump should restart/alarms should stop.*

Note: Gently tug on *metal end* of the lead to make sure that it is fully engaged into the socket. Do NOT pull on the lead.

Figure 9



Replacing System Controllers continued

10 If the pump restarts, skip to Step 12.

OR

10 If the pump does not restart and the Red Heart Alarm continues:

- **a** Firmly press the Silence Alarm or Test Select Button to restart the pump.*
- **b** Check the power source. Make sure that power is going to the Controller.
- **c** Make sure the perc lead is fully inserted into the socket. Gently tug on the *metal end.* Do NOT pull on the lead.

11 If the pump still does not restart, call for emergency help (dial 911 if available), then try to restart the pump using the System Controller backup system:

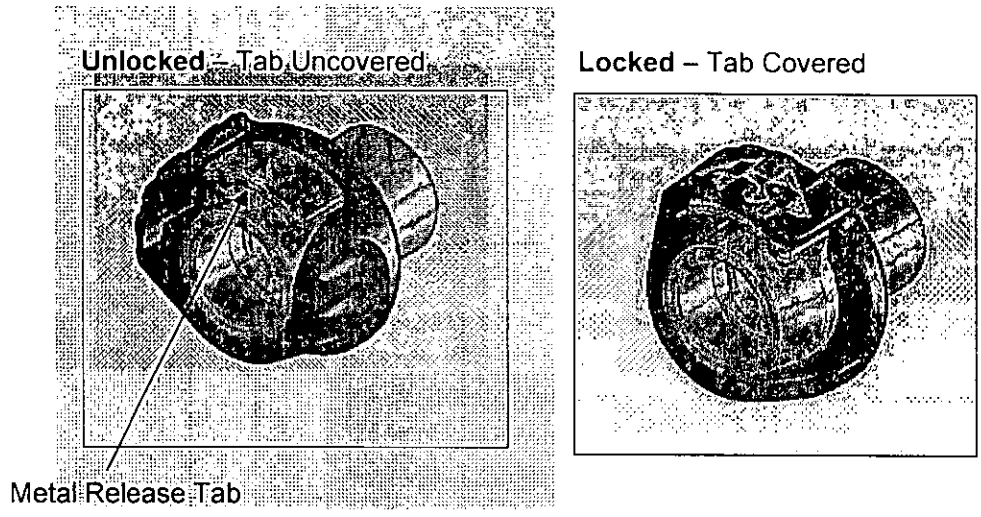
- **a** Press and hold both the Silence Alarm and Test Select Buttons at the same time. *The Red Heart Alarm will stop and you will hear a repeating cycle of one beep per second for two seconds, followed by two seconds of silence to indicate that the System Controller is operating on the backup system.*
- **b** Call your hospital contact person right away.

12 After the pump restarts, rotate the perc lock on the new, replacement Controller in the direction of the "locked" icon until the perc lock clicks into the fully-locked position (**Figure 10**).

* If the pump speed is set below 8,000 rpm, the pump will *not* automatically restart when power is restored. You will need to press either the Silence Alarm or Test Select Button to restart the pump if it is set below 8,000 rpm.

Replacing System Controllers continued

Figure 10



13 Disconnect the power source from the original System Controller. *It will stop alarming once power is disconnected.*

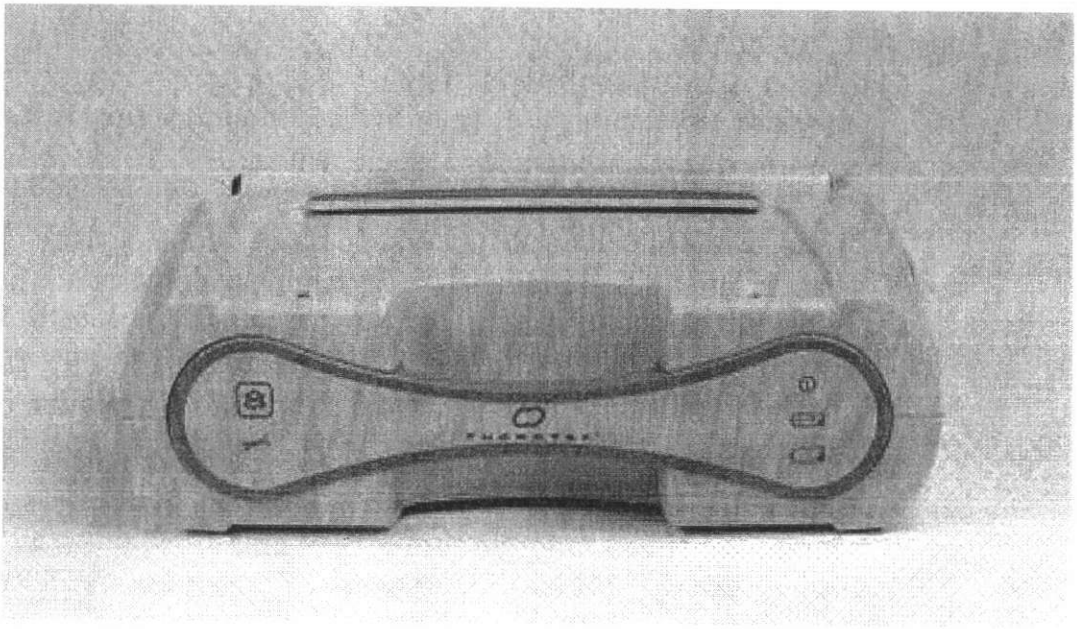
14 Return the old, original System Controller to your hospital contact person and get another backup System Controller.

The Power Module (PM)

The HeartMate Power Module (PM) (**Figure 11**) is designed to:

- Provide power to the HeartMate II LVAS during tethered operation (when connected to AC mains electrical power).
- Provide power to the Display Module when the optional Display Module is in use.
- Connect the option Display Module to the System Controller for monitoring purposes, when the Display Module is in use.
- Echo System Controller alarms.

Figure 11



Setting Up the Power Module Before Use

Before using the HeartMate Power Module (PM) for powering the LVAS and the optional Display Module, you must prepare the PM for use. Steps for setting up the PM include:

1. Connecting the PM's internal backup battery (required).
2. Connecting the PM's power cord to AC mains electrical power (required).
3. Waiting until the PM's internal backup battery is charged, as indicated by the green light on the PM (required).
4. Connecting the PM patient cable (required).
5. Connecting the Display Module cable (optional, if the Display Module is being used).

For detailed instructions on setting up the Power Module, see "Setting Up the Power Module (PM) Prior to Use," found in Section 2.0 of the *HeartMate Power Module IFU* (document # 103772).

Note: The PM contains an internal battery. When new the internal battery provides approximately 30 minutes of emergency backup power to the HeartMate II LVAS if AC mains power fails or is interrupted. If the PM is used in cold conditions (32-59°F, 0-19°C), the backup battery runtime may be reduced to a minimum of 20 minutes.

The PM is shipped with its internal battery disconnected. The internal battery must be connected before initial use or any time after the PM is shipped or transported for service or maintenance. If the internal battery is not connected, it cannot provide emergency backup power to the LVAS. Indicator symbols on the front panel of the PM light up to indicate the charge status of the internal backup battery. See *Power Module Alarms,* page 46.

WARNING !

- Connect the HeartMate Power Module (PM) only to properly-tested and grounded (3-prong) AC mains outlets that are dedicated to PM use. Do not use outlets that are controlled by a wall switch. Do not use an adapter plug or portable multiple socket outlet (power strip) for ungrounded wall outlets.
- Do NOT connect both the AC and DC input cables to the Power Module at the same time.
- Do not use the PM in the presence of flammable anesthetic agents, or an explosion could occur.
- Keep the PM away from water or moisture. If the PM has contact with water, shower spray, wet surfaces, rain/snow, etc., the LVAD may stop, you may receive a serious electrical shock, or the Power Module may fail to operate properly.
- Connectors should be kept clean and dry. Do not expose connectors to water, moisture, rain/snow, dirt, etc. when making or breaking connections.

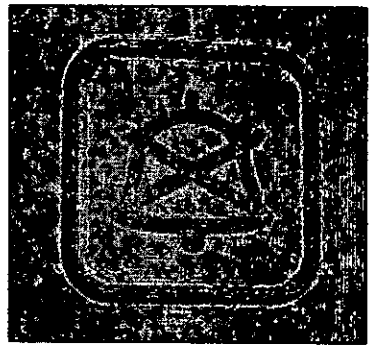
After the PM is plugged in and the "Patient" cable is connected to the "♥" socket, the PM should be ready to use. However, before using the PM for the first time, be sure to perform a PM System Self Test. See *Performing a PM System Self Test* below.

Performing a PM System Self Test

Perform a PM system self test before using the PM for the first time and at least once daily to ensure that the PM is working properly. Follow these to perform a PM System self test:

1 Press and hold the PM's Alarm Silence Button ⊠ (**Figure 12**) for five seconds.

Figure 12



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Performing a PM System Self Test cont.

2 Listen for the continuous audio tone and watch the front of the PM to see if all the lights come on in sequence (i.e., one-at-a-time; *not* all at once).

3 If any of the following occurs, there may be a problem with the PM and you should call your hospital contact person:

- No sound
- Anything other than a continuous audio tone (such as beeping or broken tone)
- All the lights come on at once
- All the lights remain off
- One of the lights does not come on

Using the PM to Power the LVAS

During routine operation, the HeartMate II LVAS uses one of two power sources, either: **1**) electricity when connected to the Power Module (PM) that is plugged into an AC mains electrical outlet, or **2**) battery power with a pair or rechargeable HeartMate batteries.

Note: The Emergency Power Pack (EPP) is not a routine power source. It is for emergency use only when electricity or batteries are unavailable (see *Using the Emergency Power Pack*, page 90).

Using the PM to provide power to the system is called "tethered" operation, since you are connected or "tethered" to AC power by the PM. Use the PM to power your LVAS any time you have access to AC mains electrical power and when you are relatively stationery or inactive. For example, while relaxing at home, reading, or watching TV.

The following components are needed for tethered operation:

- HeartMate Power Module (PM)
- PM power cord
- PM patient cable
- HeartMate II System Controller

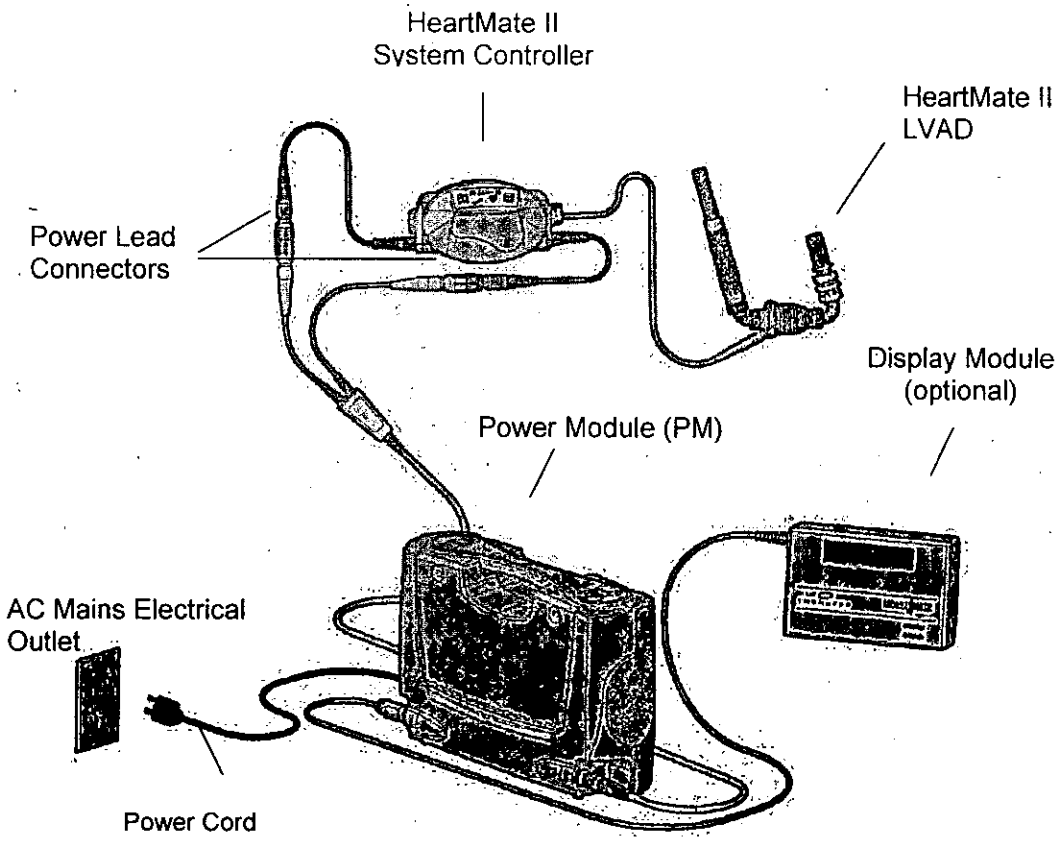
For detailed instructions on setting up the PM for tethered operation, see "Setting Up the Power Module (PM) Prior to Use," found in Section 2.0 of the *HeartMate Power Module IFU* (document # 103772).

Figure 13 shows the HeartMate II LVAS during tethered operation.

WARNING!

- Understanding how your LVAS works and knowing how to operate the system (including responding to emergencies) is needed for safe and successful use of the HeartMate II LVAS. Before using any HeartMate II equipment or accessories, be sure you are trained on their application and use.
- Read the Instructions for Use (IFUs) for the accessories used to power the HeartMate II LVAS, including the Power Module (PM), Universal Battery Charger (UBC), and the HeartMate 12 volt NiMH batteries or 14 volt Li-Ion batteries (depending on which batteries you use). Your hospital contact person will train you.
- Always use the PM to power the LVAS during sleep or when sleep is likely.

Figure 13


HeartMate II
System Controller
HeartMate II
LVAD
Power Lead
Connectors
Display Module
(optional)
Power Module (PM)
AC Mains Electrical
Outlet
Power Cord

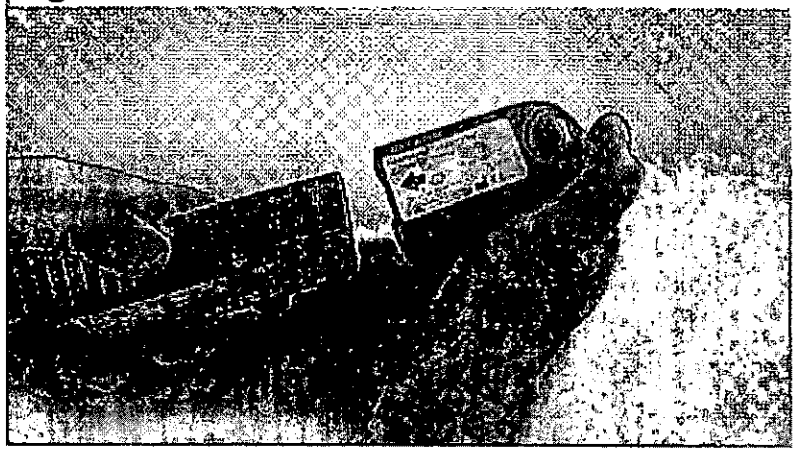
Changing from PM Power to Batteries

Changing from PM power to batteries (and vice versa) is routine procedure for HeartMate patients. Follow these steps to change from PM to battery power:

1 Place two battery clips, two charged batteries (as indicated by the green light on the UBC), and the white and black patient power lead connectors within easy reach.

2 Place the 1st charged battery into a battery clip by lining up the arrows on the battery and battery clip and pushing until the battery clicks into place (**Figure 14**).

Figure 14



3 Repeat step 2 for the 2nd battery/battery clip.

4 Unscrew the **black** System Controller/PM patient cable connectors. *The power disconnected alarm will come on: An alarm will sound one beep per second, the green power symbol will flash rapidly, and the four green battery fuel gauge lights will flash.*

5 Put aside the PM patient cable connector; then connect the battery clip connector to the **black** system controller connector. Always connect black-to-black. ***Wait until the green power symbol and battery fuel gauge lights stop flashing and the alarm stop before continuing with step 6.***

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WARNING!

- At least one System Controller power lead must be connected to a power source (PM, batteries, or EPP) at all times. Disconnecting both power leads at the same time will cause the pump to stop.
- If power to the System Controller is interrupted and pump speed is below 8,000 rpm, firmly press the Test Select or Alarm Reset switch on the System Controller to restart the pump. If pump speed is above 8,000 rpm, the pump will restart automatically once power is restored. Post implant, most patients are above 8,000 rpm.
- Do not use the PM in the presence of flammable anesthetic agents or an explosion could occur.
- Keep the PM away from water or moisture. If the PM has contact with water, shower spray, rain/snow, wet surfaces, etc., the LVAD may stop or the patient may receive a serious electrical shock or your Power Module may not work properly

6 Unscrew the **white** System Controller/PM patient cable connectors. *The power disconnected alarm will come on: An alarm will sound one beep per second, the green power symbol ⏻ will flash rapidly, and the four green battery fuel gauge lights ▮▮▮• will flash.*

7 Put aside the PM patient cable connector; then connect the battery clip connector to the **white** system controller connector. Always connect white-to-white. ***Wait until the power symbol and the battery fuel gauge lights stop flashing and the alarm stops before continuing with step 8.***

8 Place the battery clips and batteries into the holsters or carrying case.

Note: At a convenient time, recharge the batteries in the UBC. See the *HeartMate Universal Battery Charger IFU.*

CAUTION !

- When connecting cables, do not force together connectors without proper alignment. Forcing together misaligned connectors may damage them.
- Connectors should be kept clean and dry. Do not expose connectors to water, moisture, rain/snow, dirt, etc. when making or breaking connections.

9 Keep the PM patient cable connected to or nearby the PM until next use.

Note: If leaving the PM patient cable connected to the PM when not in use, place the cable where it will not become damaged, dirty, or wet; and so that it will not cause tripping or falling.

10 Place at least two additional charged batteries in the travel case.

11 Store the PM patient cable in a clean, dry location until next use. Avoid twisting or kinking the cable during storage.

Note: A *Power Change Checklist* is included in the Appendix of this manual. All PM users (including nurses, patients, and patients' caregivers) should review the checklist and retain a copy for reference, if needed. All users should know how to quickly and safely change from one HeartMate power source to another.

Changing from Batteries to PM Power

Changing from batteries to PM-powered operation (and vice versa) is routine procedure for HeartMate patients. Follow these steps to change from battery power to PM power:

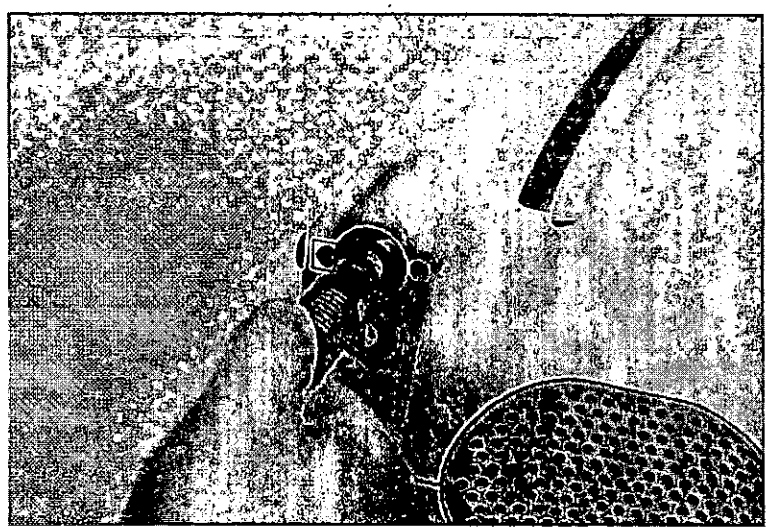
1 Ensure that the PM is plugged into a properly-tested and grounded (3-prong) AC mains outlet that is dedicated to PM use and that is not controlled by a wall switch. Do not use an adapter plug for ungrounded wall outlets. Also, do not use a portable multiple socket outlet (power strip), or you may receive a serious electric shock or your pump may stop.

2 Perform a PM System self test (see "Monitoring PM Performance and Performing a PM System Self Test" in Section 2.7 of the *HeartMate Power Module IFU* (document # 103772).

3 If the PM fails the self test, call your hospital contact person; otherwise, continue with Step 4.

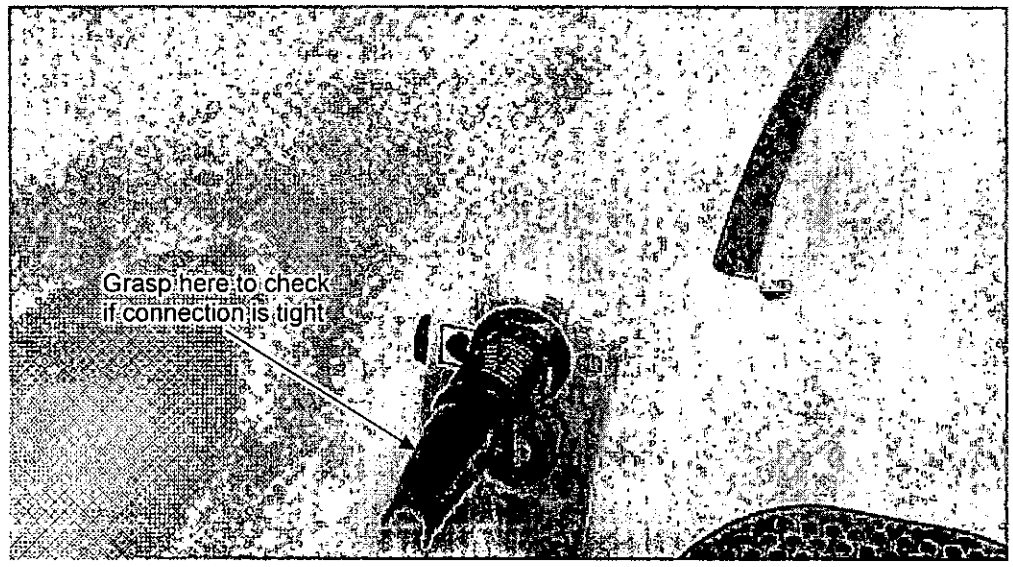
4 Line up the red dots between the PM patient cable and the " ♥ " socket located on the side of the PM, and then insert the PM patient cable into the " ♥ " socket (**Figure 15**). The cable will click into place if fully engaged in the socket. The "click" is the sound of the locking feature engaging.

Figure 15



5 After inserting the connector snugly into the socket, check that the connection is tight. Tug *gently* on the strain relief of the connector (**Figure 16**). Do NOT pull on the cable!

Figure 16



6 Place the black and white PM System Controller power lead connectors within each reach.

7 Remove the battery clips and attached batteries from the patient's holsters or carrying case.

8 Before switching from battery power, first check the charge status of each battery. Press the battery fuel gauge ▣ on each of the batteries to determine which battery has the least power (see the *HeartMate 12 Volt NiMH Battery IFU* or the *HeartMate 14 Volt Li-Ion Battery IFU*).

9 If the lights differ, disconnect the connector from the battery with the least power (fewer lights) first; otherwise, disconnect the white connector first.

10 Unscrew the **white** connector from its battery clip. *The power disconnected alarm will come on: An alarm will sound one beep per second, the green power symbol will flash rapidly, and the four green battery fuel gauge lights will flash.*

11 Put aside the battery clip and attached battery.

12 Connect the **white** PM power lead connector to the **white** System Controller connector (always connect white-to-white). ***Wait until the green power symbol stops flashing and the alarm stops before continuing with Step 13.***

WARNING !

- At least one System Controller power lead must be connected to a power source (Power Module, batteries, or EPP) at all times. Disconnecting both power leads at the same time will cause the pump to stop.
- If power to the System Controller is interrupted, and the pump speed is below 8,000 rpm, firmly press the Test Select or Alarm Reset switch on the System Controller to restart the pump. If pump speed is above 8,000 rpm, the pump will restart automatically once power is restored. Post implant, most patients are above 8,000 rpm.
- Do not use the PM in the presence of flammable anesthetic agents or an explosion could occur.
- Keep the PM away from water or moisture. If the PM has contact with water, shower spray, rain/snow, wet surfaces, etc., the LVAD may stop or the patient may receive a serious electrical shock or your PM may not work properly.

13 Unscrew the **black** connector from its battery clip. *The power disconnected alarm will come on: An alarm will sound one beep per second, the green power symbol will flash rapidly, and the four green battery fuel gauge lights will flash.*

14 Put aside the battery clip and attached battery.

15 Connect the **black** PM power lead connector to the **black** System Controller connector (always connect black-to-black).

16 Press the battery release button on one of the battery clips to release its battery.

17 Repeat Step 16 for the 2nd battery/battery clip.

18 Store the battery clips in a clean, dry location until next use.

19 Place the used batteries into the HeartMate UBC for charging. See the *HeartMate Universal Battery Charger IFU* (document # 103771).

CAUTION !

- When connecting cables, do not force together connectors without proper alignment. Forcing together misaligned connectors may damage them.
- Connectors should be kept clean and dry. Do not expose connectors to water, moisture, dirt, etc. when making or breaking connections.

Note: A *Power Change Checklist* is included in the Appendix of this manual. All PM users (including nurses, patients, and patients' caregivers) should review the checklist and retain a copy for reference, if needed. All users should know how to quickly and safely change from one HeartMate power source to another.

Power Module (PM) Backup Power

The Power Module (PM) has an internal backup battery. When new, the internal battery provides approximately 30 minutes of backup power to the HeartMate II LVAS in the event of AC mains power interruption or failure (e.g., the power cord plug is removed from the AC mains electrical outlet or a power failure during tethered operation). If the PM is used in cold conditions (32-59°F, 0-19°C), the backup battery runtime may be reduced to a minimum of 20 minutes. Over time, the internal battery may provide shorter periods of backup power.

The PM's internal backup battery remains charged as long as the PM is connected to power. If the PM is disconnected from AC mains power, the internal battery will operate the LVAS and the PM alarms until the battery is depleted. The internal backup battery automatically engages if PM input power is lost. It will automatically disengage once power is restored.

The PM's internal backup battery is rechargeable. However, it has a limited lifespan. It will be replaced during annual service/ maintenance service for the PM. See "Routine Maintenance" in Section 11.0 of the *HeartMate Power Module IFU* (document # 103772).

If using PM power during AC mains power failure, promptly switch to battery power (see *Changing from PM Power to Batteries*, page 37). If connected, the Display Module will not work during AC mains power failure. In addition, the PM's internal backup battery's charge status lights will not work

See the *HeartMate Power Module Instructions for Use* (document # 103772) for detailed warnings, precautions, and instructions on PM back up power.

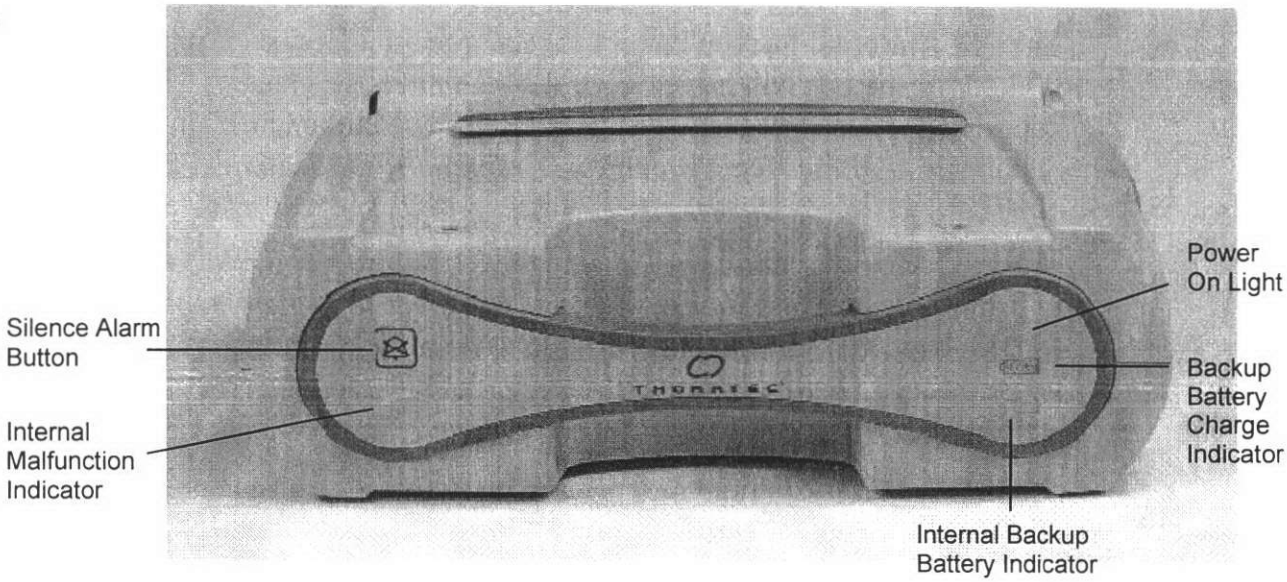
Power Module (PM) Alarms

The Power Module's internal computer is continually monitoring PM performance. It will alert you if it detects a problem. There are four alarm conditions:

- AC Fail
- Advisory LO BATT (i.e., low battery)
- Hazard LO BATT (i.e., CRITICALLY low battery)
- PM MALFUNCTION

All PM alarm conditions are accompanied by a visual indicator (lit symbol) and audio tone (**Figure 17**). Certain lights come on and different tones sound, depending on the alarm condition. See **Table 5** for a description of PM alarms and how to respond to them.

Figure 17



Note: When connected to the System Controller, the PM will duplicate any active System Controller alarms. See *System Controller Warnings Lights and Sounds,* page 18.

Table 5 Power Module (PM) Alarms

Alarm	Meaning	What You Should Do
AC FAIL "Power On" indicator changes from green to yellow  accompanied by beeping audio tone.	AC mains power off or disconnected. When new, the internal backup battery will power the HM II LVAS for approximately 30 minutes. The PM's internal backup battery will not be recharged during AC FAIL.	1 Press the PM's Alarm Silence Button ⊠ to silence the alarm (it remains silenced "forever" or until cancelled by another alarm). 2 Promptly switch to another power source, either: a new set of charged batteries or Emergency Power Pack (EPP).* 3 Call VAD Coordinator or hospital contact.
Advisory LO BATT (i.e., low battery) Yellow Internal Backup Battery Indicator  accompanied by beeping audio tone.	Less than 15 minutes of internal backup battery power remain.	1 Press the PM's Alarm Silence Button ⊠ to silence the alarm for 8 hours. 2 Promptly switch to another power source (either a new set of charged batteries or EPP).* 3 Call VAD Coordinator or hospital contact.
Hazard LO BATT (i.e., critically low battery) Red Internal Backup Battery Indicator  accompanied by continuous audio tone.	Less than 5 minutes of internal backup battery power remain.	1 IMMEDIATELY switch to another power source (either a new set of charged batteries or EPP).* 2 Call VAD Coordinator or hospital contact.
Advisory Fault Yellow Wrench Indicator  accompanied by beeping audio tone.	Internal malfunction detected within the PM.	1 Switch to another power source (either a new set of charged batteries or EPP) at earliest convenience. 2 Call VAD Coordinator or hospital contact.
Critical Fault Yellow Wrench Indicator  accompanied by continuous audio tone.	Internal malfunction detected within the PM.	1 IMMEDIATELY switch to another power source (either a new set of charged batteries or EPP).* 2 Call VAD Coordinator or hospital contact.

* If you remain connected to the PM using its internal backup battery for power, the internal backup battery indicator will turn yellow and then red as the internal battery is depleted to 15 minutes and then 5 minutes of remaining power. See "Power Module (PM) Backup Power" in Section 4.0 of the *HeartMate Power Module IFU* (document # 103772). When only 5 minutes of power remain, the PM's audio tone becomes constant and you will no longer be able to silence the alarm. Switching to another power source is the only way to silence a Red Battery Hazard Alarm.

Silence Alarm Button

Pressing the Silence Alarm Button ⊠ silences an audio alarm (see **Table 5** or list below for how long; silence periods vary by alarm type). If a new alarm condition arises during a silence period, a new audio alarm will sound. After the silence period ends, the audio alarm will resume, unless the alarm condition has been resolved. Pressing the Alarm Silence Button only silences the alarm; it does NOT fix the alarm condition.

· **Echo of System Controller Alarm**	5 Minutes
· **AC Fail**	No time out (silence lasts "forever" or until cancelled by another alarm)
· **Yellow Battery**	8 Hours
· **Red Battery**	Alarm Silence/Reset not possible if connected to LVAD
· **Battery Fault**	2 Minutes
· **Yellow Wrench**	8 Hours for non-critical faults. Alarm Silence/Reset not possible for some alarms (see **Table 5**).

Routine PM Inspection, Cleaning & Maintenance

The HeartMate PM requires little planned maintenance. However, it should be inspected routinely for the safest and best possible performance:

- **Once a day**, perform a PM System Self Test (see *Performing a PM System Self Test,* page 33).
- **Any time you switch** from batteries to PM-powered operation (before going to bed, for example), inspect the connector pins and sockets for damage, dirt, grease, etc.
- **At least once a week**, inspect the power cord used to connect the PM to an electrical outlet. Make sure the cord is not kinked, split, cut, cracked, or frayed. Do not use the cord if it shows signs of damage. Obtain a replacement from Thoratec, if needed.
- **At least once a week**, inspect the PM patient cable used to connect to the PM. Make sure the PM patient cable is not kinked, split, cut, cracked or frayed. Do not use the cable if it shows signs of damage. Obtain a replacement from Thoratec, if needed.
- **Once a month**, inspect the pins and sockets of the PM patient cable/lead connectors for damage, dirt, grease, etc.
- **Once a month**, inspect the pins and sockets of the "DC Input" cable for damage, dirt, grease, etc.
- **At least once a year**, bring the HeartMate PM to an authorized service technician for a thorough inspection and cleaning that includes (but need not be limited to) the following:
  - Functional test of device
  - Cleaning and inspection of all internal components
  - Replacing internal backup battery
  - Replacing PM patient cable

IMPORTANT! Be sure the PM's internal backup battery is re-connected after service/maintenance or shipping/transportation. See "Connecting the Internal Backup Battery," in Section 2.1 of the *HeartMate Power Module IFU* (document # 103772).

- **Periodically, and as needed**, clean the exterior surfaces of the PM using a clean, damp (not wet) cloth. You may use a mild, non-abrasive cleaner if necessary. Do NOT immerse the PM in water or liquid. NEVER clean the PM while using it to power your pump; switch to battery power first. Before cleaning the PM, UNPLUG all connections.

WARNING !

Do NOT clean or service the following equipment while it is in use or while you are connected to it: System Controller, PM, PM cable, Display Module, System Monitor, HeartMate batteries, battery clips, Emergency Power Pack (EPP), and EPP cable.

CAUTION !

Service and maintenance of the HeartMate Power Module should be performed only by service personnel who are trained and authorized by Thoratec Corporation.

Do NOT attempt to clean or repair equipment on your own. If you discover damage or contamination on the pins/sockets, do NOT attempt to clean them yourself. Report the condition to your hospital contact person. Cleaning and service should be performed only by trained and authorized technicians.

Do NOT disconnect the connectors between the System Controller and percutaneous lead. The pins/sockets for this connection should be inspected only during System Controller replacement. See page 27 for instructions on replacing System Controllers.

Note: Avoid blocking or covering the air vents on the PM when the device is in use. Blocking or covering the vents can affect device performance.

HeartMate Batteries

HeartMate batteries are the other routine power source for the HeartMate II LVAS. During battery-powered operation, the LVAS is powered by a pair of direct current (DC) batteries that are inserted into battery clips (**Figure 19**). The battery clips and attached batteries can be worn in holsters, one under each arm, or in a carrying case worn at the waist.

Using batteries to power the system is called mobile operation, since you are not connected to electricity. Use battery power when you want to be mobile and relatively active. For example, while shopping, running errands, or performing other activities outside or away from home.

Two types of HeartMate batteries can power the HeartMate II LVAS. Either one pair of:

- HeartMate 12 volt nickel metal hydride (NiMH) batteries; or
- HeartMate 14 volt lithium ion (Li-Ion) batteries.

Both batteries work in the same manner. However, there are differences in color, size and weight (**Figure 18**). Differences are described in the table below. Also see pages 54 and 55 for approximate run time for 12 volt NiMH batteries and 14 volt Li-Ion batteries.

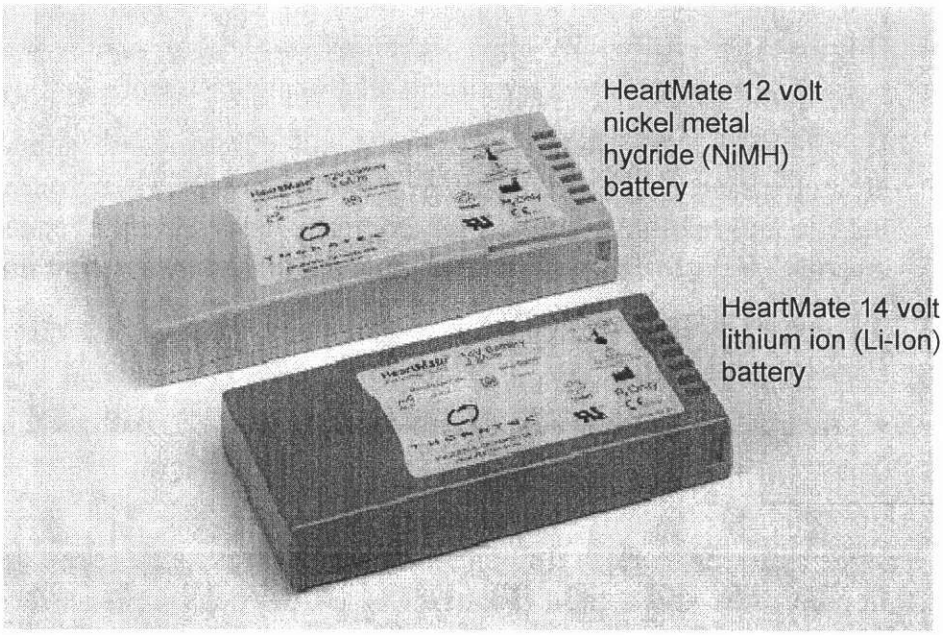
Table 6 HeartMate Battery Characteristics

	Catalog Number for Set of 4	Part Number for Single Battery	Size/ Weight	Color
HeartMate 12 NiMH Volt Batteries	2060	102474	L: 180mm (7.1") W: 76mm (3.0") H: 25mm (1.0") 0.65kg (1.44lb)	Light Grey*
HeartMate 14 Volt Li-Ion Batteries	2465	102515	L: 150mm (6.3") W: 76mm (3.0") H: 25mm (1.0") 0.50kg (1.1lb)	Dark Grey*

* Batteries are the same color as their corresponding clips.

HeartMate Batteries continued

Figure 18



WARNING !

- HeartMate 12 volt NiMH batteries are compatible with both the HeartMate II and HeartMate XVE LVAS. They can power both the HeartMate II and HeartMate XVE systems. The HeartMate 14 volt Li-Ion batteries (see the *HeartMate 14 Volt Li-Ion Instructions for Use*) are NOT compatible with the HeartMate XVE system. HeartMate 14 volt Li-Ion batteries can only power the HeartMate II LVAS.
- Use only Thoratec-supplied 14 volt battery clips to connect with HeartMate 14 volt Li-Ion batteries. Other battery clips will not transfer electrical power to the HeartMate II LVAS. See the *HeartMate 14 Volt Li-Ion Battery IFU* (document # 103770) for information on 14 volt battery clips.
- Ensure you are using the correct batteries before relying on them for power. Using the wrong batteries for an incompatible system will result in pump failure.

HeartMate Batteries continued

HeartMate batteries only work with matching clips (12 volt NiMH batteries use 12 volt clips and 14 volt Li-Ion batteries use 14 volt clips). Since 12 volt and 14 volt batteries and battery clips are NOT interchangeable, your hospital contact person will give you only one type of HeartMate battery and clip at the same time. Be sure to read the manual that comes with your batteries. It contains detailed warnings, precautions, and instructions

Figure 19

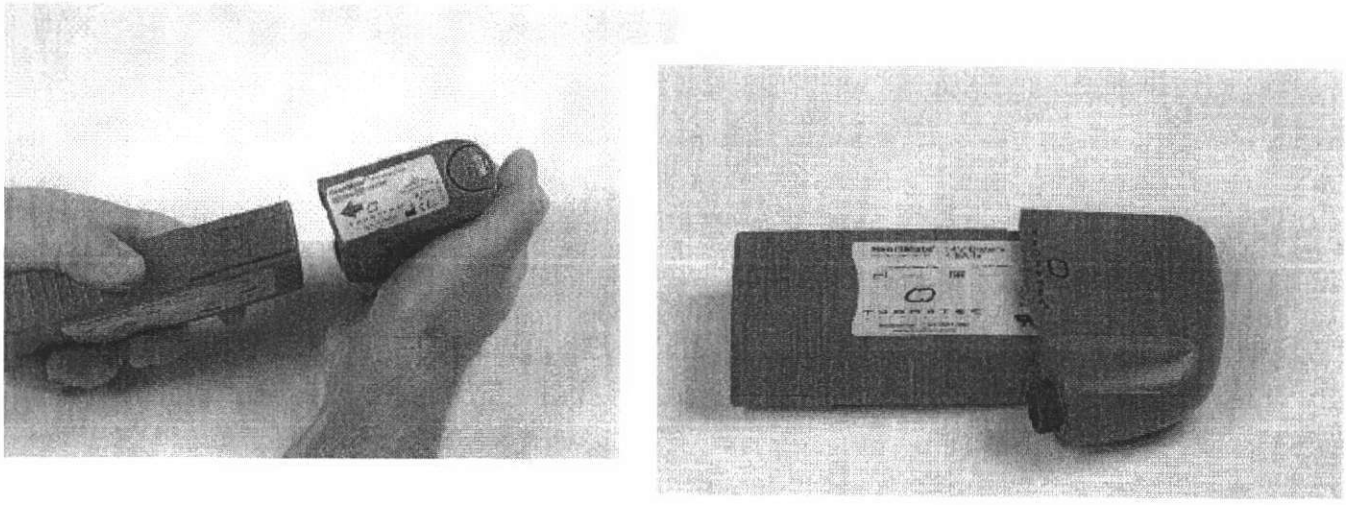
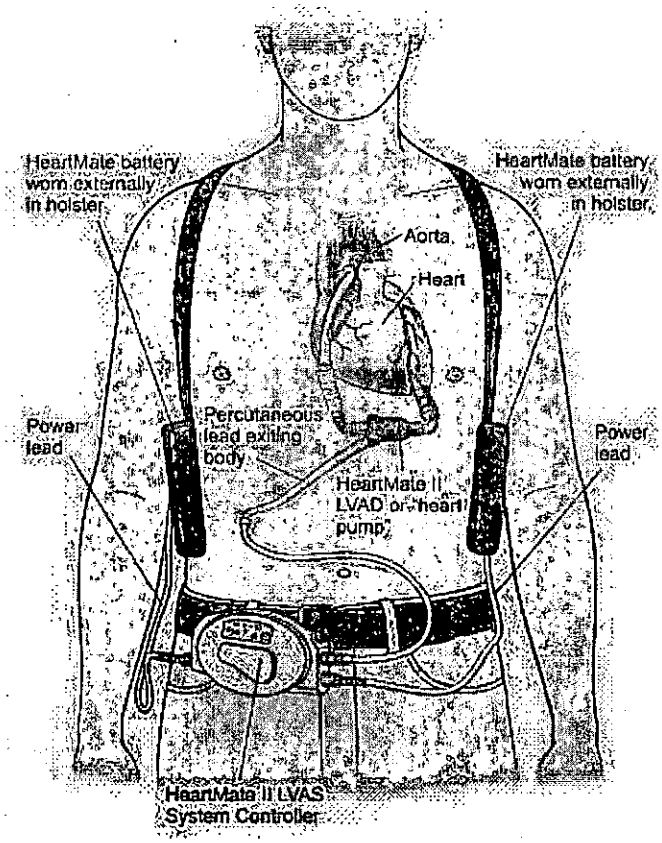


Figure 20



For 12 Volt NiMH Batteries

One pair of new HeartMate 12 volt NiMH batteries will provide at least six hours of support.

Batteries will last for less time if you are active or emotionally stressed. As batteries get older, they will power the system for shorter periods of time. If a pair of HeartMate12 volt NiMH batteries does not give at least four hours of support, take both out of service and tell your hospital contact person. See *Monitoring Battery Life*, page 65.

Batteries are used in pairs. However, it is possible to run the system with one battery for a very short period (60 seconds or less). For example, while switching from batteries to PM-powered operation, or vice versa.

For 14 Volt Li-Ion Batteries

One pair of new HeartMate 14 volt Li-Ion batteries will provide six to ten hours of support.

Batteries will last for less time if you are active or emotionally stressed. As batteries get older, they will power the system for shorter periods of time. If a pair of HeartMate 14 volt Li-Ion batteries does not give at least four hours of support, take both out of service and tell your hospital contact person. See *Monitoring Battery Life*, page 66.

Batteries are used in pairs. However, it is possible to run the system with one battery for a very short period (60 seconds or less). For example, system operation will continue on a single battery while switching from battery-powered to PM-powered operation, or vice versa.

WARNING !

- At least one System Controller power lead must be connected to a power source (PM, batteries, or EPP) at all times. If both System Controller power leads are disconnected at the same time, the pump will stop.
- It is essential that neither System Controller power lead (used to connect the System Controller to a power source) is ever disconnected from power for more than 60 seconds. If disconnected for more than 60 seconds, the risk of pump stoppage increases.

During battery-powered operation, the System Controller shows overall power capacity (for both batteries) on the System Controller's battery fuel gauge. The System Controller's battery fuel gauge will tell you if the batteries are running low. If the current power source is low, the Controller will prompt you switch to a different power source (a new pair of charged batteries or the PM). The status of an individual battery can be checked any time by pressing the battery fuel gauge on that battery (see *Checking a Battery's Charge Status*, page 58).

WARNING !

- HeartMate 12 volt NiMH batteries work with both the HeartMate II and HeartMate XVE systems. See the **Appendices** for HeartMate 12 volt NiMH battery characteristics.
- The HeartMate 14 volt Li-Ion batteries (see the *HeartMate 14 Volt Instructions for Use*) are NOT compatible with the HeartMate XVE system. HeartMate 14 volt Li-Ion batteries can only power the HeartMate II LVAS.
- Ensure you are using the correct batteries before relying on them for power. Using the wrong batteries for an incompatible system will result in pump failure.

Charging New Batteries for the First Time

You must charge each HeartMate battery before use (this includes the first use). It takes approximately four hours or less to charge a depleted battery. Batteries are charged in the HeartMate Universal Battery Charger (UBC), which can charge up to four batteries at once.

Depending on how long a battery has been is storage, the on-battery fuel gauge may not work until after the battery goes through its first charge cycle (see *Checking Battery Charge Level* on the following page).

See the *HeartMate Universal Battery Charger IFU* (document # 103771) or page 72 of this manual for instructions on charging HeartMate batteries.

WARNING!

HeartMate 14 volt Li-Ion batteries must be charged at least once by the end of the month marked on the label placed on battery packaging (box and protective bag). If a 14 volt Li-Ion battery is not charged by this date, battery operating time may be affected, which can cause the pump to stop. Do not use a HeartMate 14 volt Li-Ion battery if it has not been charged by the date indicated. It has expired. See the *HeartMate 14 Volt Battery IFU* (document # 103770).

Checking a Battery's Charge Status

Once properly charged (see instructions in the *HeartMate Universal Battery Charger IFU*), a new HeartMate battery should be ready for use. But, before using any battery, first make sure that it has finished charging and check its status with the battery fuel gauge.

The battery's fuel gauge (**Figure 21**) shows a battery's charge status using five green lights. Each light represents approximately 20% of available power. When the battery is charged and ready for use, all five lights turn on. Fewer lights illuminate as power is depleted. When battery power drops below 10%, only one green light comes on and it will be blinking.

Follow these instructions for checking a battery's charge status:

1 Go to the Universal Battery Charger (UBC); locate a battery inside one of the charging pockets.

2 Look at the three lights next to the charging pocket for this battery. A green light means the battery is charged and ready for use.

Note: A green light next to the pocket is the only assurance the battery is 100% charged. If the yellow light is on, the battery is still charging. If the red light is on, there is a problem with the battery – do not use it. See Section 3.0, "Charging Batteries," in the *HeartMate Universal Battery Charger IFU* for full details.

3 If the pocket light is green, remove the battery from the charging pocket.

4 Find the battery symbol on the battery's fuel gauge.

5 Press and hold the battery symbol for five second ().

1 **Figure 21**

6 If all five of the green fuel gauge lights come on, the battery is between 80 - 100% charged (**Table 7**).

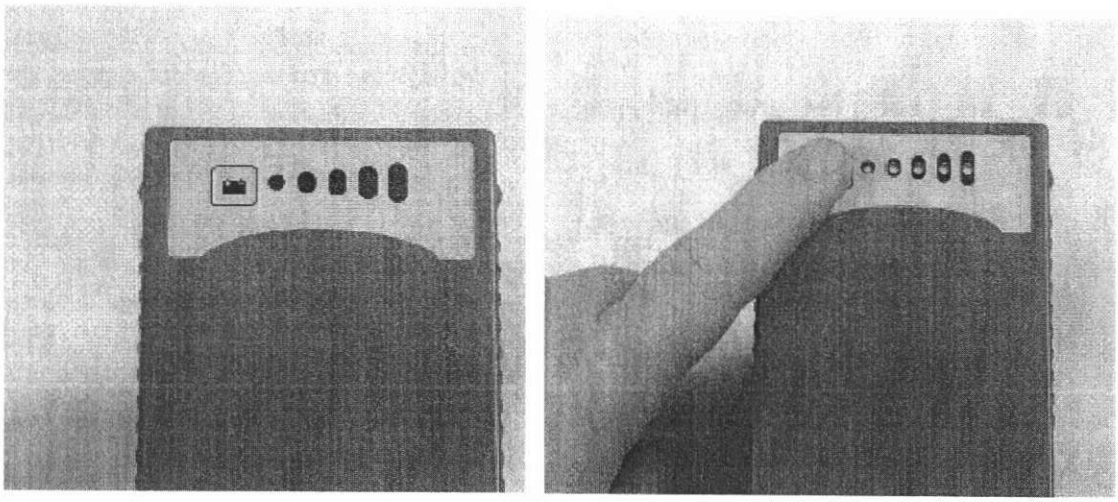
OR

V71

6 If four or fewer lights come on, the battery is not yet ready for use. Return it to the pocket for more charging.

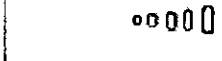
Note: If the fuel gauge continues to show four or fewer lights after additional charging, the battery may be defective. Do not use it. Contact your hospital contact person for information.

Figure 21



A battery's fuel gauge may show five lights illuminated, while the UBC still indicates a "charging yellow" light. This is normal, because five lights on the battery does not indicated "fully-charged," but rather, 80 – 100% charged. See **Table 7** below.

Table 7 Battery Fuel Gauge

Number for Lights Illuminated	Meaning
 1 Light (blinking)	Approximately 10% or less of power remains. Do NOT use if battery has one blinking light.
 1 Light (steady)	Approximately 10–20% of power remains
 2 Lights	Approximately 20–40% of power remains
 3 Lights	Approximately 40–60% of power remains
 4 Lights	Approximately 60–80% of power remains
 5 Lights	Approximately 80–100% of power remains

If all of the lights come on, except for one in the middle of the sequence, it may be that the light emitting diode (LED) for this light has broken or burned out. If this happens, call your VAD Coordinator or hospital contact person.

Note: Depending on how long a battery has been is storage, its fuel gauge may not work until after the battery undergoes its first charge (see Section *Checking a Battery's Charge Status,* above).

Exchanging Used Batteries with Charged Batteries

Replacing used, depleted batteries with a charged pair is a routine procedure. With experience the steps become familiar. Your GoGear wearable accessories allow you to exchange used batteries with charged batteries without having to take off the accessory and without disrupting power leads. See "Changing Batteries" in the Instructions for Use (IFU) that came with your GoGear holster vest, modular belt, or consolidated bag for guidelines on how to do this.

WARNING!

- At least one (1) System Controller power lead must be connected to a power source (batteries, Power Module, or Emergency Power Pack) at all times. If both System Controller power leads are disconnected at the same time, the pump will stop.
- It is essential that neither System Controller power lead (used to connect the System Controller to a power source) is ever disconnected from power for more than 60 seconds. If disconnected for more than 60 seconds, the risk of pump stoppage increases.
- Never disconnect both batteries at the same time or the pump will stop.
- HeartMate 14 volt Li-Ion batteries are for use exclusively with the HeartMate II LVAS. They are NOT compatible with the HeartMate XVE system and cannot power the HeartMate XVE LVAS. Do NOT use HeartMate 14 volt Li-Ion batteries with the HeartMate XVE system. See Appendix 1 of the *HeartMate 14 Volt Li-Ion Battery IFU* (doc # 103770) for HeartMate 14 volt Li-Ion battery characteristics.
- Ensure you are using the correct batteries before relying on them for power. Using the wrong batteries for an incompatible system will result in pump failure.

Follow these steps for exchanging HeartMate batteries:

1 Obtain two charged HeartMate batteries from your travel case or PM and place them within easy reach.

Note: If getting batteries from the UBC, make sure the light near the charging pockets for each battery is green (i.e., battery ready for use) (see *Checking a Battery's Charge Status,* page 58).

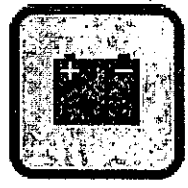
2 Press and hold the battery symbol ▣ on each of the new batteries; make sure they are charged and ready for use (see *Checking Battery Charge Level*).

3 Grasp the battery clip (and attached battery) for one of the two batteries currently powering the system. Remove the clip and attached battery from the holster/carrying case and place it within each reach.

Note: Do NOT remove the battery from its clip at this time.

4 Locate the battery fuel gauge symbol ▣ on one of the batteries that is currently in use (**Figure 22**).

Figure 22



5 Press and hold the battery symbol on the 1st battery for five seconds to see how much battery power remains for this battery (i.e., count the number of lights that come one).

6 Repeat Steps 3 – 5 for the 2nd battery currently in use.

7 Determine which of the two batteries has the least power (i.e., fewer lights).

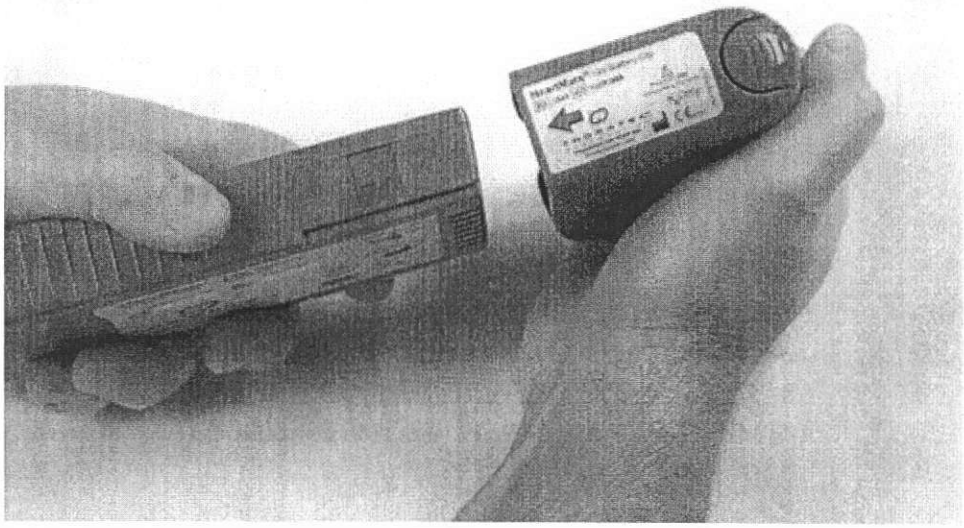
8 If both batteries have the same amount of power, switch either battery; otherwise, exchange the battery with the FEWER number of lit lights first:

- **a** Press the battery release button on the battery clip.
- **b** Withdraw the battery from its clip. *The System Controller will sound a once-per-second BEEP and the green power symbol and fuel gauge lights will flash.*

9 Pick up one of the charged batteries; locate the orange arrow on the battery.

Note: Make sure to pick up a charged battery and not one of the old, depleted batteries.

Figure 23



10 Line up the orange arrow on the new battery with the orange arrow on the empty battery clip, so that the two arrows are facing each other (**Figure 23**).

11 Slide one of the new, charged batteries into the empty battery clip. The battery should "click" into place. However, after inserting it, gently pull on the battery and try to remove it from the clip. If properly and fully inserted, the battery will remain inside. In addition, the once-per-second BEEP will stop if the battery is properly inserted. It may take a few seconds for the beeping to stop.

12 Remove other discharged battery and repeat steps 9 – 11 to exchange the 2nd battery.

13 Return the clips (now containing the charged batteries) to holsters or carrying case.

14 Make sure the charger is plugged in and turned on ("I") *before* placing batteries into pockets for charging.

15 Place the depleted batteries into the UBC for recharging. See the *Universal Battery Charger IFU.*

WARNING !

Make sure the Universal Battery Charger (UBC) is plugged in and turned on ("I") before placing batteries into the pockets for charging.

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Power Saver Mode

If there is less than five minutes of power left in your batteries, the pump will automatically slow down and begin pumping at a reduced speed. This is called Power Saver Mode. When this happens, the System Controller's Red Battery light comes on, along with a CONTINUOUS AUDIO TONE.

Running at reduced speed is a critical situation. You may become dizzy or short of breath. It is important that you switch to a new pair of charged batteries or to another power source (PM or EPP) right away. Switching to a different power source will stop the alarm and return the pump its original speed.

Note: If the alarm does not stop after changing batteries or switching to a different power source, call you hospital contact person. You may need to replace the System Controller or PM patient cable.

Cleaning Batteries and Battery Clips

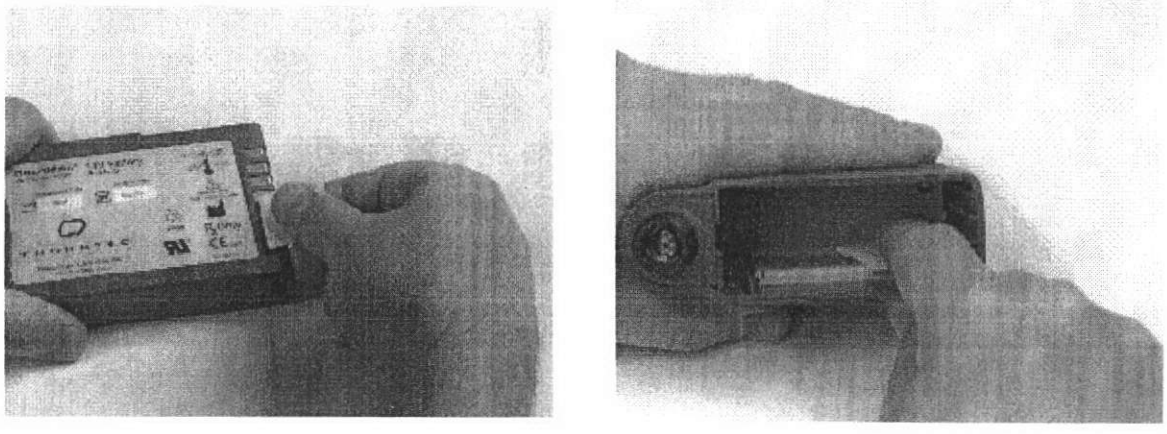
HeartMate batteries and battery clips need periodic inspection and cleaning. Follow these guidelines and instructions for inspecting and cleaning them:

- **Once a week**, inspect batteries for physical damage. Do NOT use batteries that appear damaged. Damaged batteries must be replaced.
- **Once a month**, check the manufacture date on the label on all batteries to see if any batteries are older than three years. If it has been three years or more since a battery was manufactured, that battery has expired. Do NOT use expired batteries. Expired batteries must be replaced.
- **Once a month**, check the number of use/charge cycles for each battery to see if it has exceeded 360 cycles. Do NOT use batteries that have exceeded 360 cycles. Batteries that have exceeded 360 cycles must be replaced. To find out the number of use/charge cycles for a battery, place it into one of the Universal Battery Charger (UBC) charging pockets.

The information will be displayed on the UBC display panel (see *Viewing Battery Information on the Universal Battery Charger (UBC) Screen*, page 75).

- **Once a month**, clean the metal battery contacts and contacts inside of the battery clips using a lint-free cloth or cotton swab that has been moistened (not dripping) with rubbing alcohol (**Figure 24**). Do NOT clean batteries while using them to power the LVAS. Allow the alcohol dry before using newly cleaned batteries or clips.
- **Periodically and as needed**, clean the exterior surfaces of batteries (EXCEPT the contacts) using a clean, dry cloth. Do NOT use liquids (e.g., water or liquid cleaning solvent) to clean batteries. Do NOT immerse batteries in water or liquid. Do NOT clean batteries or battery clips while using them to power your pump; switch to PM power first.

Figure 24



WARNING !

Do NOT clean batteries or battery clips while using them to power your pump; switch to PM power first.

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Monitoring Battery Life

A number of factors influence battery life for a HeartMate battery. The two most important are the number of uses and the number of months since the battery was manufactured. The month and year of manufacture appears on every HeartMate battery label.

If a battery is stored and used according to the conditions outlined in its Instructions for Use, the battery should be usable for approximately 360 cycles *or* 36 months from the date of manufacturer, whichever comes first. After this time, battery performance cannot be guaranteed. Call your hospital contact person when either of these milestones is reached for a HeartMate battery.

Universal Battery Charger (UBC)

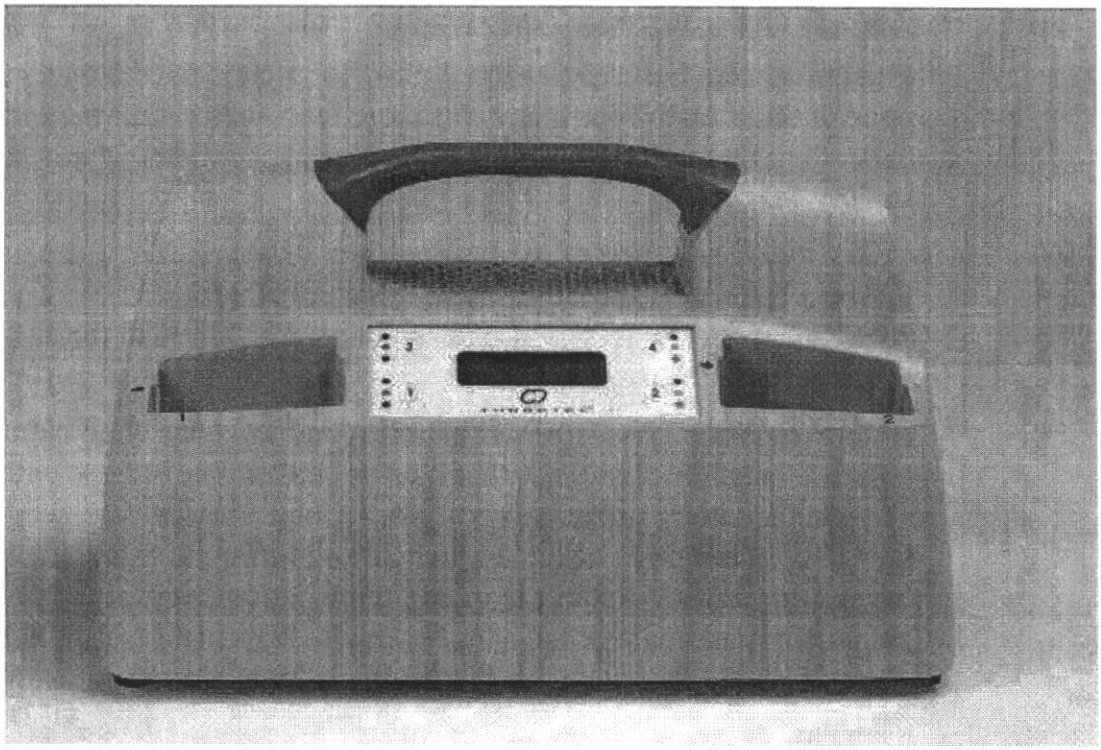
The HeartMate Universal Battery Charger (UBC) (**Figure 25**) is designed to charge HeartMate batteries that are used to power the LVAS during mobile operation. Specifically, the HeartMate UBC can:

- Charge up to four HeartMate batteries in four hours or less.
- Monitor the need for calibration and calibrate individual HeartMate batteries.
- Perform diagnostic testing on up to four HeartMate batteries at once.

CAUTION !

Use only the HeartMate Universal Battery Charger (UBC) to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries.

Figure 25



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Setting Up the Universal Battery Charger (UBC) Before Use

Before using the HeartMate Universal Battery Charger (UBC) to charge HeartMate batteries, the UBC must be plugged in and turned on. In addition, before using the charger, you may want to select the language/display panel setting that is best for your needs. See "Setting Up the Universal Battery Charger Prior to Use," found in Section 2.0 of the *HeartMate Universal Battery Charger IFU* (document # 103771) for detailed instructions on setting up the charger.

WARNING !

- Connect the HeartMate Universal Battery Charger (UBC) only to properly-tested and grounded (3-prong) AC outlets. Do not use an adapter plug for ungrounded wall outlets.
- Ensure the UBC is connected to AC power and is turned "on" before placing batteries into the pockets for charging.

Charging Batteries (Overview)

The HeartMate UBC can charge up to four HeartMate batteries at once. It takes up to four hours to charge from one to four batteries, depending on the charge status of the battery(ies) being charged. Be sure to plan battery use and charging with the four-hour recharge period in mind.

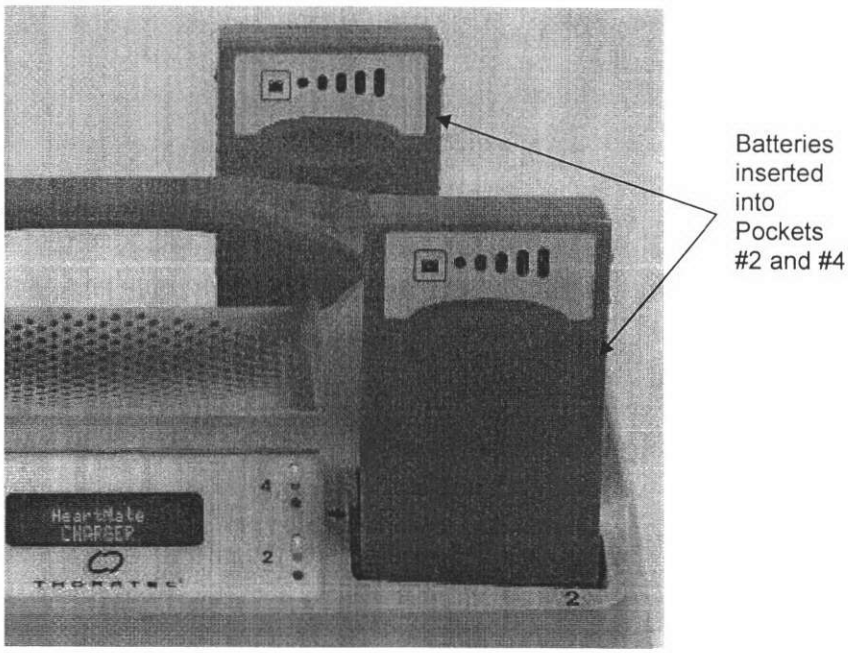
For best battery performance, leave charged batteries in the charging pockets until ready for use. Leaving charged batteries in the charger will not damage them.

Both HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries utilize a "smart" technology that measures available battery power and counts battery usage/charge cycles. Once a battery is placed into the UBC's charging pocket (**Figure 26**), the charger immediately checks that battery's status by reading the battery's on board computer chip. Information about the battery (charge status and total number of use/charge cycles) can be viewed on the UBC's display panel by pressing the number button for that pocket.

CAUTION !

- The Universal Battery Charger (UBC) cannot test or charge the black sealed lead acid (SLA) HeartMate batteries originally used with the HeartMate Power Base Unit (PBU). Black SLA HeartMate batteries should be charged in the PBU.
- Do NOT charge HeartMate 12 volt NiMH batteries in the HeartMate PBU. Use the UBC to charge HeartMate 12 volt NiMH batteries. Any other battery charger will damage HeartMate 12 volt NiMH batteries.

Figure 26



Depending on the status of the battery that is inserted, one of three lights (yellow, green, or red) located near the number button for this pocket will come on (**Figure 27**).

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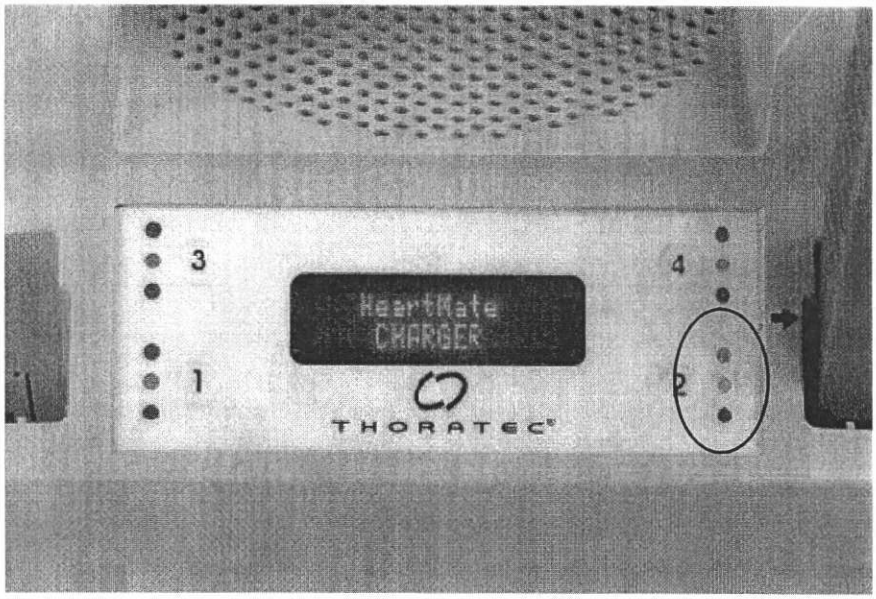
Figure 27



Charge Status Lights for Pocket #2 (circled)

A **yellow** light means that the battery is being tested, charged, or calibrated. **Green** means the battery is charged and ready for use. **Red** means the battery is defective or that there is a problem with the charger. Do not use a battery that has a red light. See **Table 8** below for a summary of UBC light color codes. Color codes are the same for both 12 volt NiMH batteries and 14 volt Li-Ion batteries.

Table 8

UBC Pocket Light Indicators	
Light Color	**Status/Meaning**
Green	Battery is ready for use
Yellow	Battery is undergoing test, charge, or calibration
Yellow (Blinking)	Battery requires calibration cycle
Red	Battery or charging pocket is defective, Do not use battery

A battery's fuel gauge may show five lights illuminated, while the UBC still shows a "charging yellow" light. This is normal, as five lights on the battery does not indicated "fully-charged," but rather, 80 – 100% charged. See **Table 8**.

WARNING!

- Ensure you are using the correct batteries before relying on them for power. Using the wrong batteries for an incompatible system will result in pump failure.
- The HeartMate 12 volt NiMH batteries can power both the HeartMate II LVAS and the HeartMate XVE LVAS.
- The HeartMate14 volt Li-Ion batteries are NOT interchangeable betweens the HeartMate II and the HeartMate XVE II systems. HeartMate 14 volt Li-Ion batteries are for use exclusively with the HeartMate II LVAS. They are NOT compatible with the XVE system and cannot power the XVE LVAS. Do NOT use HeartMate 14 volt Li-Ion batteries with the HeartMate XVE LVAS.

Note: Any time the "HeartMate CHARGER" message is displayed, the display panel will slowly dim, turn off for two seconds, and then brighten again to full brightness. This helps to prolong the life of the display panel. You may use the UBC during this process.

Charging Batteries (Procedure)

Follow these instructions for charging HeartMate batteries (12 volt NiMH batteries or 14 volt Li-Ion batteries).

1 Obtain one or more HeartMate batteries.

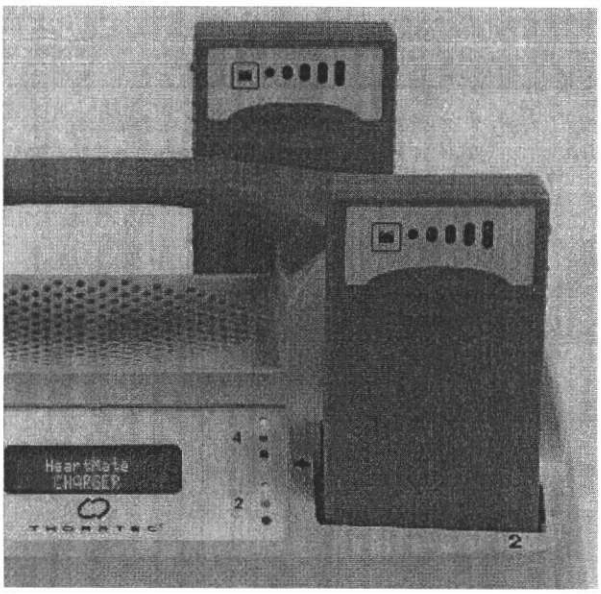
CAUTION !

- Do not attempt to charge non-HeartMate batteries in the HeartMate Universal Battery Charger (UBC). Doing so may damage the charger or the batteries, or injure you.
- Before inserting a NiMH or Li-Ion battery into the UBC for charging, inspect the battery for signs of damage. Do not use batteries that appear damaged.

2 Place one of the HeartMate batteries into one of the four battery charging pockets, with the battery fuel gauge on the top and facing forward (**Figure 28**).

Note: Do not force a battery into a charging pocket. Batteries will fit only one way into a pocket (with the battery's battery fuel gauge at the top and facing forward. A beep and one of the pocket lights coming on (red, yellow, or green) confirms the battery is properly placed in a pocket.

Figure 28



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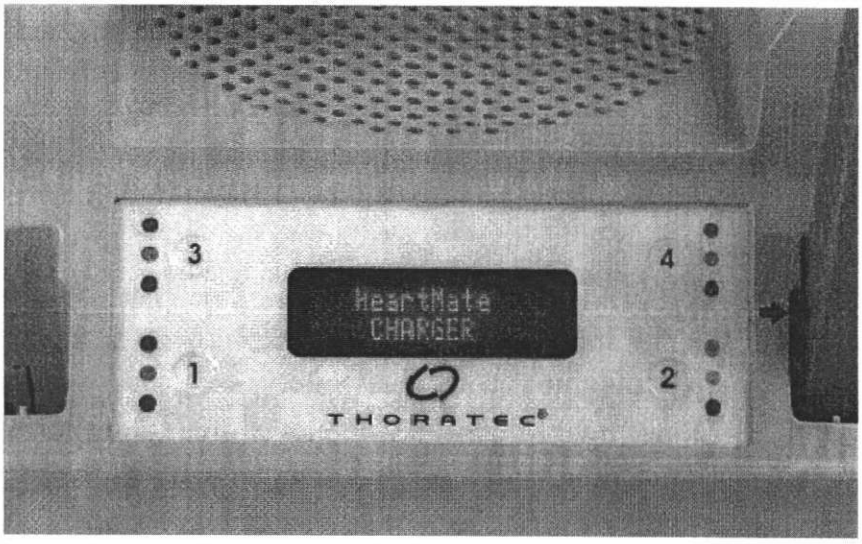
3 After hearing the beep, look at the three lights (yellow, green, and red) next to the number button for this pocket (**Figure 29**).

Note: The UBC has four charging pockets. Numbers 1 – 4 on the front panel of the charger correspond to the location of each pocket. For example, "1" on the panel stands for the front left pocket; "2" stands for the front right pocket; "3" stands for the rear left; and "4" stands for the rear right pocket.

Figure 29



4 Identify which of the three lights (yellow, green, or red) comes on for this pocket.

5 If the **yellow** light comes on, the battery is actively charging. Do nothing with the battery. Leave the battery in the pocket to continue charging and skip to Step 7. If a blinking yellow light is observed, the battery needs calibration (see *Calibrating HeartMate Batteries* on page 79.

Note: The yellow light will remain on until the battery becomes charged. Once the battery becomes charged, the yellow light turns off and the green light comes on.

OR

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5 If the **green** light comes on, the battery is already charged and ready for use. Either remove the battery for immediate use, or leave the battery in the pocket until needed.

Note: Leaving charged batteries in the charger will not damage them.

OR

5 If the **red** light (or no light at all) comes on, there is a problem with the battery or the charging pocket.

Note: Remove the battery and reinsert it into the same pocket. If again there is a red light (or no light), insert the battery into a different pocket. If the battery cannot be charged in a different pocket, the battery is defective Do not use the defective battery. Contact your VAD Coordinator or hospital contact person for help and for a replacement, if needed. See *Monitoring Battery Performance* on page 82 for information on advisory messages and troubleshooting, including how to read alarm codes when a red light comes on.

6 After approximately four hours, look at the three lights near the charging pocket for this battery.

Note: It takes up to four hours to charge one to four batteries, depending on the original charge status of the battery(ies) being charged.

7 If the **green** light is on, the battery is charged and ready for use.

OR

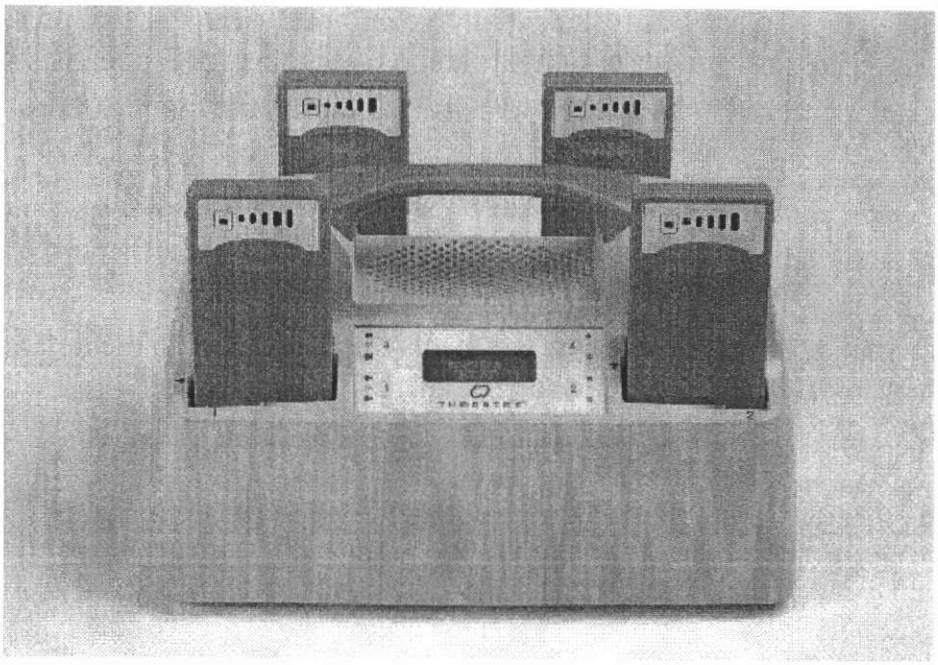
7 If the **yellow** light is on, the battery is still charging.

OR

7 If the **red** light is on, there is a problem with the battery and/or the charger interrupted the charging cycle for some reason. See *Monitoring Battery Life* on page 66 for how to handle red light conditions.

8 Repeat Steps 2 – 8 for as many as three more batteries, to charge up to four batteries at the same time (**Figure 30**).

Figure 30



Viewing Battery Information on the Universal Battery Charger (UBC) Screen

To check a battery's charge status, place the battery into a charging pocket, then press and release the number button for that pocket. The following will appear on the display panel (**Figure 31**):

- Pocket Number
- Battery symbol
- Percentage of available charge

For example, if approximately 50% of the battery's power is available (i.e., battery is 1/2 charged), half of the battery symbol is filled and "50%" appears on the screen.

After five seconds, the display returns to the default screen ("HeartMate CHARGER"), unless the number button for this pocket is pressed again. Pressing the button a second time brings up the total number of use/charge cycles (see immediately below).

To see how often a battery has been used/charged, press and release the number button while the Charge Status Screen is still on. The following will appear on the display panel (**Figure 32**):

- Pocket Number
- Total number or uses/charges for this battery
- How much power the battery can potentially hold if fully charged (measured in mAh)

After 10 seconds, the display panel returns to the default ("HeartMate CHARGER") screen (**Figure 29**).

Figure 31

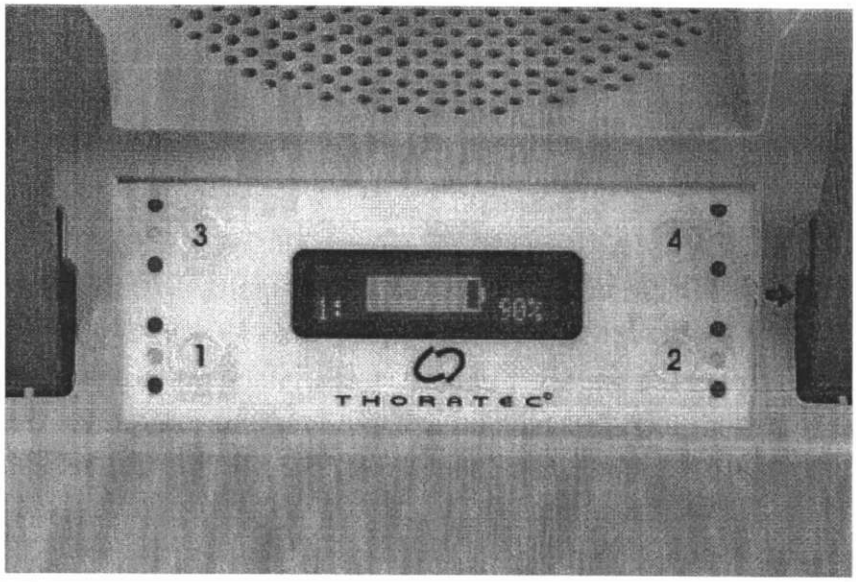
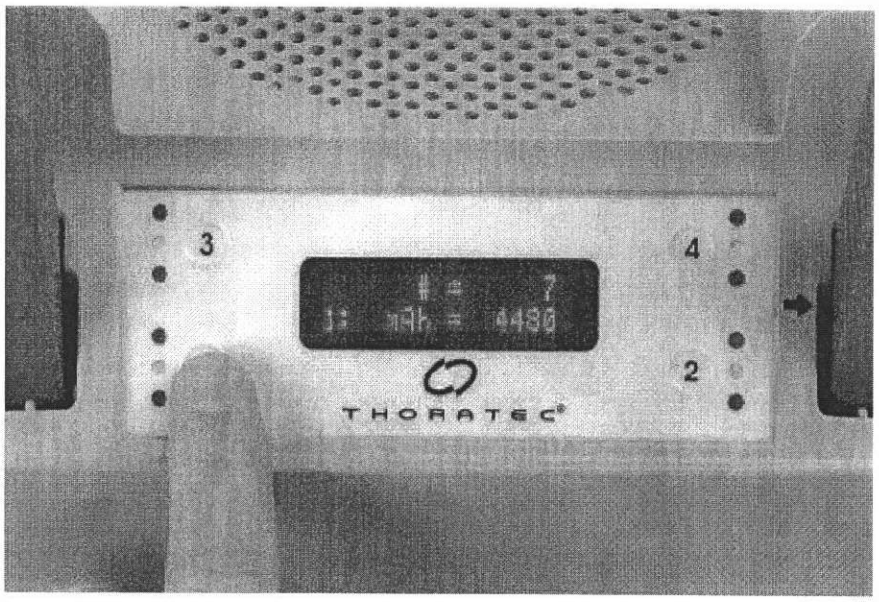


Figure 32



If a battery is being calibrated (see *Calibrating HeartMate Batteries* on page 79), the pocket number and a split battery symbol appear on the display panel when the number button for that pocket is pressed (**Figure 33**).

Note: Five seconds after pressing the button, the display returns to the default ("HeartMate CHARGER") screen (**Figure 29**).

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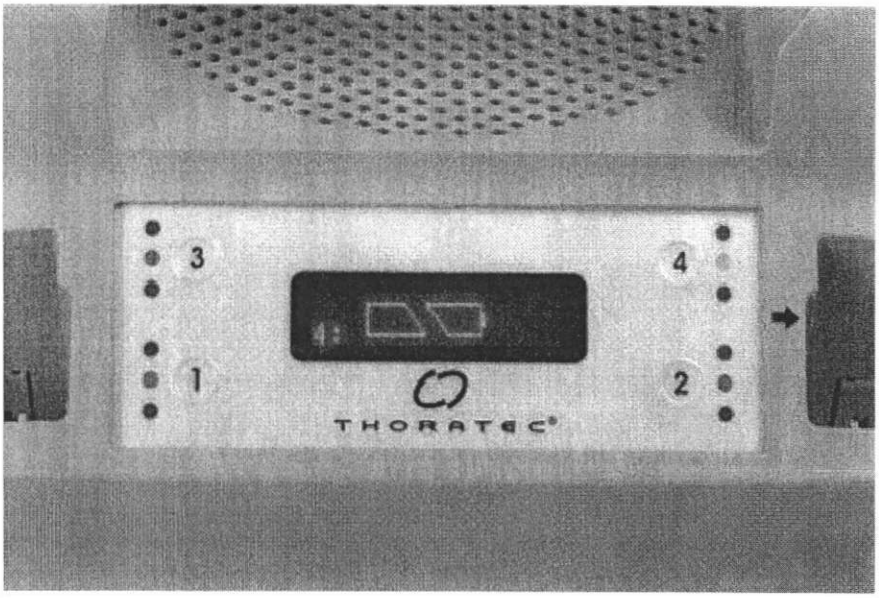
Figure 33



See the **Appendix/Table 11** in the back of this manual for a complete list of display panel symbols and messages.

Calibrating HeartMate Batteries

HeartMate 12 volt NiMH batteries and 14 volt Li-Ion batteries use a "smart" technology that measures available battery power and counts battery usage/charge cycles. Periodically (approximately every 70 battery uses), the battery may sense that it needs to calibrate its battery fuel gauge. Calibration helps keep the battery's fuel gauge accurate.

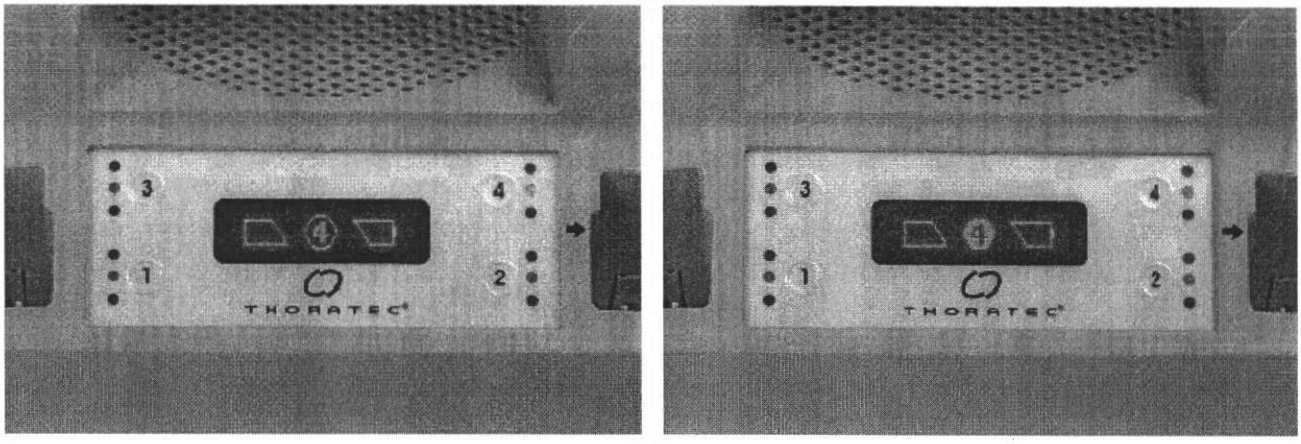
The battery must be placed into the Universal Battery Charger (UBC) to be calibrated. During calibration, the UBC drains the battery of all electrical energy and then recharges it. Battery calibration can take up to 12 hours, and only one battery can be calibrated at a time. During calibration, the other three HeartMate batteries can be charged as usual.

If a battery needs to be calibrated, the UBC will tell you when that battery is inserted into one of the charging pockets. The following occurs if calibration is recommended:

- The yellow light for this pocket blinks
- A split battery symbol and the pocket number for this battery flashes on the display panel screen (**Figure 34**).

Note: The circled number will switch between a filled and unfilled circle as the display panel screen flashes.

Figure 34



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You have the choice of calibrating the battery when prompted or waiting for another, more convenient time (e.g., at night while sleeping). If you choose to not calibrate, ten seconds after the prompt, the charger will continue with a normal charge cycle for this battery (see *Charging Batteries,* page 72). It is OK to use a battery (once recharged) if you delayed its calibration. But, you should calibrate it as soon as possible.

If you choose to calibrate the battery, and then decide to cancel calibration, you can cancel the process by removing the battery from its pocket. **If you do remove a battery before calibration is complete, make sure to recharge and check the battery before using it.** Removing a battery before calibration ends may result in a depleted battery (the on-battery fuel gauge will reflect this status).

Note: It is important to calibrate a battery as soon as possible after being prompted to do so. This helps ensure the best possible battery performance. Be sure to have enough charged batteries when planning for calibration, which can take up to 12 hours. For example, under normal conditions, having four charged batteries will allow you to exchange batteries twice during a 12-hour calibration cycle.

Follow these steps to calibrate a HeartMate battery (12 volt NiMH batteries or 14 volt Li-Ion batty):

1 Receive a calibration prompt from the charger (blinking yellow light, split battery symbol on display panel screen) (**Figure 34**).

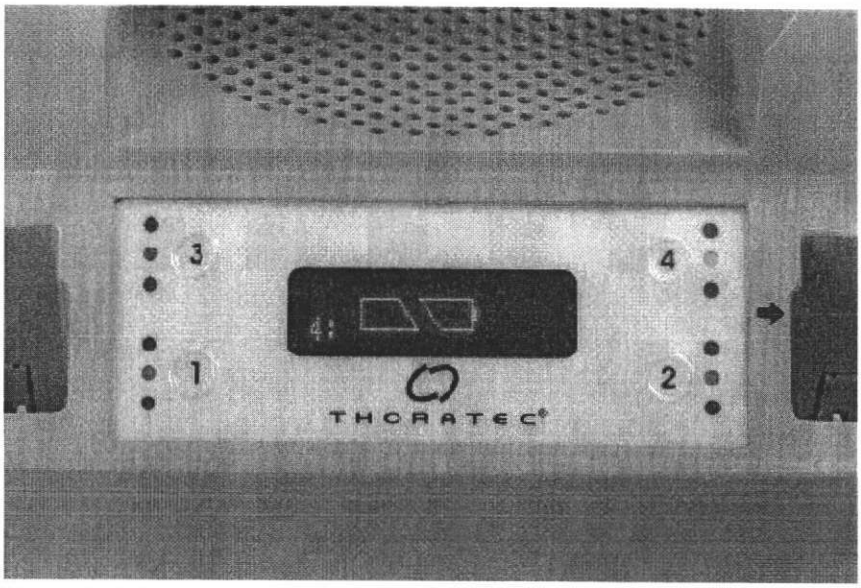
2 If you do not want to calibrate the battery now, do nothing. After ten seconds, the charger will continue to charge the battery as usual (see *Charging Batteries,* page 72).

OR

2 If you do want to calibrate the battery now, within 10 seconds of the start of the blinking yellow light, press and release the number button for this pocket.

Note: During calibration, the yellow light for this pocket remains on and "HeartMate CHARGER" appears on the display panel screen, unless the number button for this pocket is pressed. Pressing the number button during calibration brings up the calibration status screen for the battery (**Figure 35**). Once calibration is complete, the yellow light turns off and the green light comes on. Green means the battery is charged and ready for use.

Figure 35



CAUTION !

Leave a calibrating battery in the Universal Battery Charger (UBC) for the entire calibration cycle. Removing the battery before it is fully calibrated may result in a depleted battery (the on-battery fuel gauge will reflect this status).

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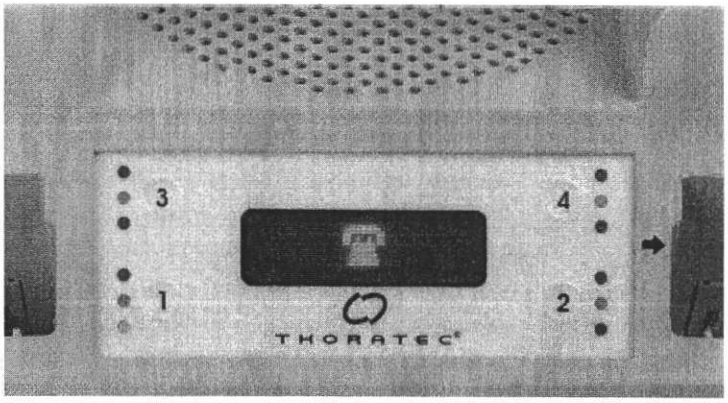
Monitoring Battery Performance

The Universal Battery Charger (UBC) is continually monitoring its own performance and that of any battery placed into a pocket. Actual or potential problems, or "faults," appear as "advisory messages" on the charger's display panel screen (**Figure 36**), "Call Service" message). See the **Appendix/Table 11** in the back of this manual for a summary of English text and graphic symbols appearing on the UBC's display panel screen.

Figure 36



The UBC can detect a problem or "fault" condition with up to four charging pockets at once (with or without batteries inside), or with the entire charger unit. The UBC will alert you immediately of any problems.

If the UBC detects a pocket fault, the red light for the affected pocket(s) (with or without battery(ies) inside) will come on. In addition, the charger will immediately stop charging/calibrating the battery(ies) that are inside the affected pocket(s). See "Monitoring Performance," found in Section 5.0 of the *HeartMate Universal Battery Charger IFU* (document # 103771) for a summary of fault conditions and how to respond to each.

Note: Do not use a damaged or defective UBC. Until you have a safe and reliable way to charge batteries, use an alternate power source to power your HeartMate system. For example, use the HeartMate PM exclusively until the UBC is repaired or replaced.

CAUTION

Use only the HeartMate Universal Battery Charger (UBC) to charge HeartMate batteries. Other battery chargers may damage HeartMate batteries.

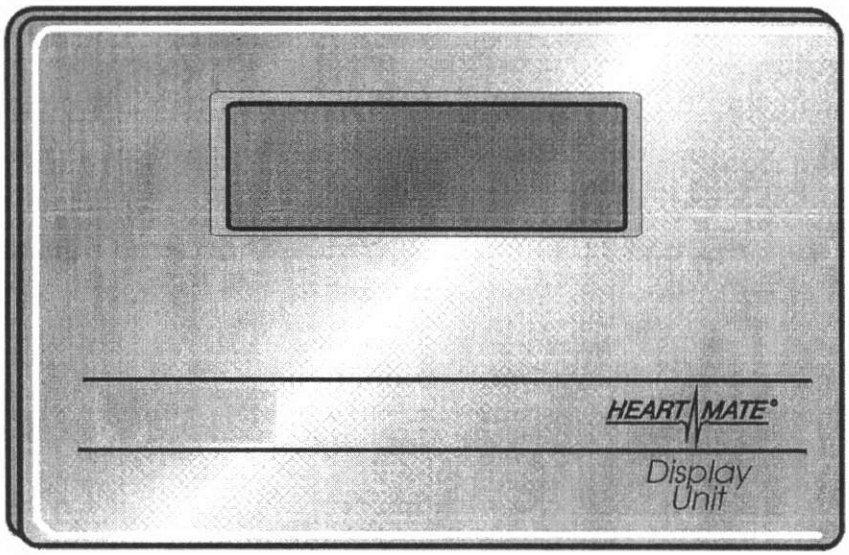
Display Module

When connected to the Power Module (PM) and System Controller, the optional Display Module (**Figure 37**) reports data received from the System Controller through the PM. See the *HeartMate Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on using the optional Display Module with the PM.

For HeartMate II patients, the Display Module screen displays the following:

- Current pumping mode (fixed or power saver mode)
- Current pump speed in revolutions per minute (RPM)
- Pulsatility Index (PI) (your hospital contact person can explain this)
- Estimated flow in liters per minute (LPM)
- Power in watts (W)

Figure 37



Display Module continued

Setting Up the Display Module for Use with the PM

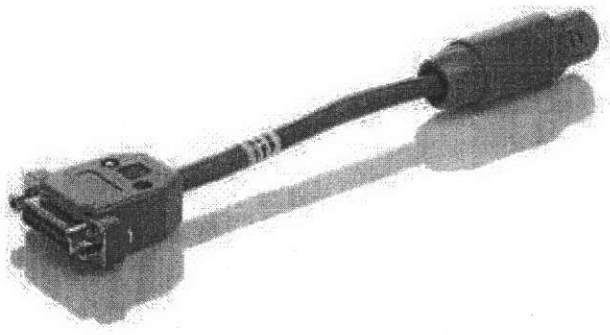
Follow these steps for setting up the Display Module for use with the PM:

1 Ensure the PM patient cable is attached to the PM. See "Connecting the PM Power Cord and PM Patient Cable," section 2.2 of the *HeartMate Power Module IFU* (document # 103772).

2 Ensure that the PM is plugged into a properly-tested and grounded (3-prong) AC mains outlet that is dedicated to PM use and that is not controlled by a wall switch. Do not use an adapter plug for ungrounded wall outlets. Also, do not use a portable multiple socket outlet (power strip), or you may receive a serious electric shock or the pump may stop.

3 Obtain the Display Module cable adapter (**Figure 38**) from product packaging.

Figure 38



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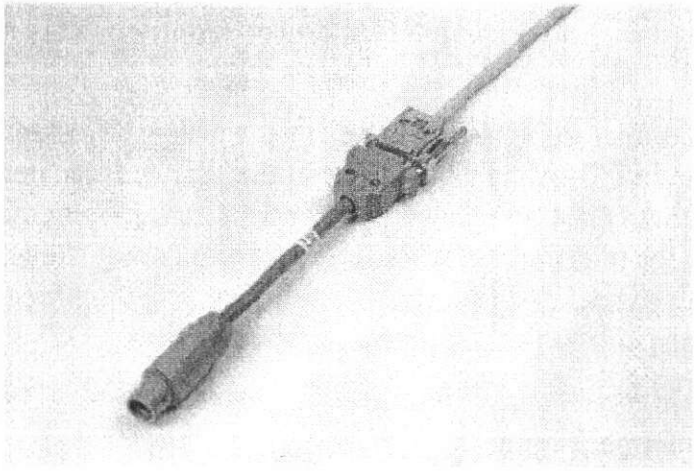
Display Module continued

4 Insert the male end of the adapter into the female end of the data cable receptacle of the Display Module. Firmly press together the connectors to ensure a tight connection (**Figure 39**).

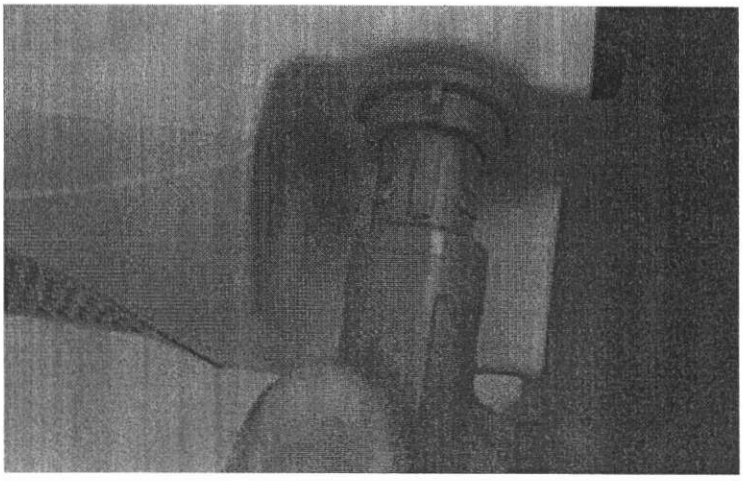
Figure 39



5 Tighten the two thumb screws on the adapter connector to secure the connection.

6 Align the grooves between the adapter connector and the " ▭ " socket found on the side of the PM (**Figure 40**); insert the connector into the " ▭ " socket

Figure 40



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Display Module continued

Note: The PM (with its round receptacle for the Display Module/System Monitor interface) replaces many of the features of the Power Base Unit (PBU). You will need an adapter (described above) to connect the Display Module to the PM (see Steps 3 – 6). Call your VAD Coordinator or hospital contact person for a Thoratec adapter, if needed.

7 Reference the Display Module screen. If you are connected to the PM and System Controller, the following should immediately appear once the cable is successfully connected (otherwise the screen remains blank):
- Current pumping mode (i.e., fixed or power saver mode)
- Current pump speed, in revolutions per minute (RPM)
- Pulsatility index (PI)
- Estimated flow in liters per minute (LPM)
- Power in watts (W)

8 If you are connected to the PM and System Controller and the screen appear as described above, the Display Module is functioning properly and ready for use with the PM.

OR

8 If you are connected to the PM and System Controller and the screen do not appear as described, check the following:
- The PM patient cable is fully inserted into the " ♥ " socket on the side of the PM.
- The Display Module adapter cable is fully inserted into the " ▣ " socket on the side of the PM
- The System Controller power leads are properly connected (white-to-white and black-to-black).
- The male end of the Display Module adapter is not fully connected into the female end of the data cable receptacle, of the Display Module.

9 If the screen still does not appear, call your hospital contact person for assistance.

Note: At any time when the Display Module is in use, if an alarm condition arises, an alarm message immediately replaces performance data on the Display Module screen. **See the following page for a summary of Display Module alarms.**

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Table 9 Display Module Alarm Messages

ALARM MESSAGES	MEANING	SYSTEM CONTROLLER WARNING LIGHTS & SOUNDS	WHAT YOU SHOULD DO
LOW Flow for X min.	Pump has stopped or is not working right.	 RED HEART with CONTINUOUS AUDIO TONE	1 Make sure System Controller is connected to pump and PM cable is connected to PM. 2 Switch to fully-charged batteries. 3 Call emergency services (dial 911). 4 Follow emergency procedures (page 114).
LOW VOLTAGE	Less than 5 min. of battery power left.	 RED BATTERY with CONTINUOUS AUDIO TONE	Change batteries **one at a time**. If batteries are not available, switch to PM or EPP. **Note**: Pump speed will slow down to save power until the alarm clears (see Power Saver Mode, page 64). **Warning**: Do NOT disconnect both power leads at the same time or your pump will stop.
Power Cable Disconnected	One of the power leads is disconnected.	FLASHING POWER SYMBOL  *and* FLASHING BATTERY FUEL GAUGE LIGHTS with 1 beep every second	Check for loose power leads. If on PM power, check that power lead is not disconnected or damaged. Check that the System Controller power lead is damaged.

continued

Display Module continued

Table 9 (continued)

ALARM MESSAGES	MEANING	SYSTEM CONTROLLER WARNING LIGHTS & SOUNDS	WHAT YOU SHOULD DO
LOW VOLTAGE Advisory	Less than 15 min. of battery power left. System Controller not getting enough power.	 YELLOW BATTERY symbol with 1 beep every 4 seconds	Switch to fully-charged batteries or switch to PM or EPP. **Warning**: Do NOT remove both batteries at the same time or your pump will stop.
DRIVER CELL LOW Advisory	System Controller's battery module is low on power.	 YELLOW CONTROLLER CELL symbol with 1 beep every 4 seconds.	Replace System Controller battery module (page 25).
REPLACE SYSTEM DRIVER Advisory	System Controller is operating in back-up mode.	REPLACE SYSTEM DRIVER (on Display Module). BROKEN AUDIO TONE with repeating cycle of 1 beep every second for 2 seconds, followed by 2 seconds of silence.	1 Replace System Controller page 27) 2 Call your hospital contact person. **Note**: The System Controller is sometimes referred to a "System Driver."
LOW SPEED	Pump is operating below the low speed limit set by your doctor.	**Warning**: Low Speed (on System Monitor or Display Module) 1 beep every 4 seconds.	1 Confirm that doctor has not ordered this speed setting. 2 Call your hospital contact person.

Using The Emergency Power Pack (EPP)

The EPP is a large battery. Use it to power your system if you lose all electrical power (for example, during a power outage caused by a storm or severe weather). The EPP is mandatory for HeartMate II patients. Each EPP provides about 12 hours of support under "normal" conditions (e.g., reading a book, casual walking). The EPP will last for less time if you are more active or if you have increased emotional stress. See **Figure 41** to see EPP connections.

Each EPP is labeled with an expiration date. Do NOT use an expired EPP.

Note: Before using your EPP for emergency power, use all available charged batteries first. In this way, the EPP is saved until absolutely necessary.

1 Open the top of the EPP and read the instructions inside.

2 Plug the cable provided with the EPP into the cable receptacle located on top of the EPP.

3 Unscrew the **white** System Controller connector from the battery or PM. *An alarm will sound.*

WARNING!

- At least one System Controller power lead must be connected to a power source (Power Module, batteries, or EPP) at all times. Disconnecting both power leads at the same time will cause the pump to stop.
- If power to the System Controller is interrupted, and the pump speed is below 8,000 rpm, firmly press the Test Select or Alarm Reset switch on the System Controller to restart the pump. If pump speed is above 8,000 rpm, the pump will restart automatically once power is restored. Post implant, most patients are above 8,000 rpm.
- Do not use the PM in the presence of flammable anesthetic agents or an explosion could occur.
- Keep the PM away from water or moisture. If the PM has contact with water, shower spray, rain/snow, wet surfaces, etc., the LVAD may stop or the patient may receive a serious electrical shock or your PM may not work properly.

4 Connect the **white** System Controller connector to the **white** EPP connector. *The alarm will stop.*

5 Unscrew the **black** System Controller connector from the battery or PM. *An alarm will sound.*

6 Connect the **black** System Controller connector to the black EPP connector. *The alarm will stop.*

7 You are now connected to the EPP (**Figure 41**).

8 Contact your hospital contact person or local emergency service provider to make other arrangements for powering the pump if the power outage is expected to last longer than 12 hours.

9 If you use the EPP longer than three hours, it must be replaced.

Note: Discard used EPPs according to local, state or federal laws and regulations for battery disposal.

OR

9 If you use the EPP for less than three hours, record how long you used it on the EPP Usage Log that is included in the EPP.

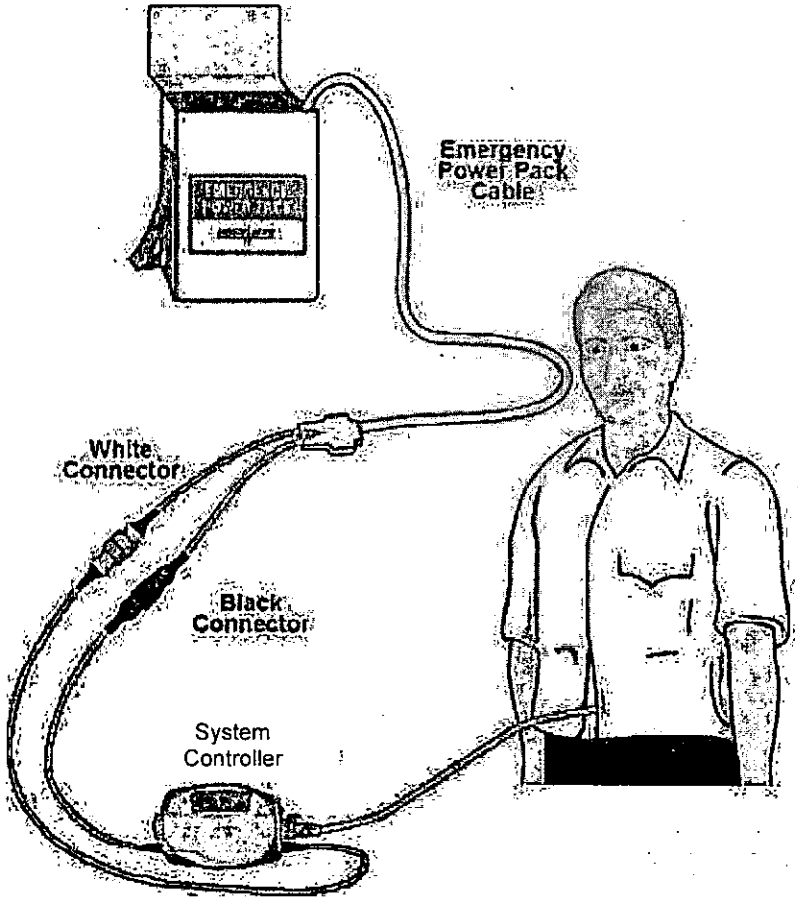
Note: The EPP may be used again, but only until the total time used equals a maximum of three hours. *For example, you could use the EPP for 1½ hours the first time, ½ hour the second time, and 1 hour the third time (for a total of three hours) before having to replace it.*

WARNING

- At least one System Controller lead must be connected to a power source (PM, batteries, or EPP) at all times. Disconnecting both Controller leads at the same time will cause your pump to stop.
- Loss of power will cause the pump to stop. Power must be restored as soon as possible. If power cannot be restored, immediately start hand pumping with the hand pump.

Using The Emergency Power Pack (EPP) continued

Figure 41



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Using The Emergency Power Pack (EPP) continued

CAUTION !

- When connecting leads, do not force together connectors without proper alignment. Forcing together misaligned connectors may damage the connectors.
- Never use tools to tighten connectors; hand tighten only. Using tools may damage the connectors.
- Do not allow the connector ends to get dirty or wet.
- To prevent deterioration or damage to the EPP:
  - Do NOT leave or store EPP in hot areas (car trunks, etc.) or EPP life will be shortened.
  - Do NOT use EPP beyond its expiration date.
- Do NOT use the EPP in temperatures below 32° F (0° C) or above 122° F (50° C), or it may fail suddenly. If your EPP stays below room temperature (68-72° F, 20-23° C) during use, it will run the pump for less than 12 hours. At the low end of the temperature range (32° F, 0° C), run time will be reduced.
- Do NOT transport or store the EPP in temperatures below 5° F (0 – -15° C) or above 122°F (50° C), or it may fail suddenly. If your EPP stays below room temperature (68-72° F, 20-23° C) during use, it will run the pump for less than 12 hours. At the low end of the temperature range (32° F, 0° C), run time will be reduced.
- Dispose of expired or used EPPs according to local, state or federal laws and regulations. Do NOT incinerate.

Living With Your Heart Pump

Keeping Your Home Safe

Before being discharged from the hospital, your home will be checked by the hospital's Discharge Planner. He or she will check for safety and electrical readiness using a checklist similar to the following:

___ Is the home free of clutter and dangerous objects?

___ Are there stairs? If so, how many?

___ Is there a bedroom on the first floor?

___ Is there a bathroom on the first floor; and does the bathroom have a shower? *Remember, no tub baths while implanted with the pump and showers only after the doctor gives permission.*

___ Is the home electrically safe, with enough safe, grounded (3-prong), and working electric outlets? (at least one outlet must be dedicated to powering the PM).

___ Does the home have adequate telephones for emergency communication (for example, speed dial for emergency calling)?

___ Are any occupational or physical therapy aids needed (for example, shower chair)?

___ Has the electric company been notified in writing of the need for priority power restoration in the event of a power loss?

Note: After your home passes the safety check, you and your family are responsible for making sure that it stays safe. If you have any questions or concerns about keeping your home safe, talk with your hospital contact person. If you are not comfortable testing your home's electrical system, you can hire a local electrician to do it for you.

Note: Consider keeping a land-line (non-portable) telephone in your home for emergency calls (unless your hospital contact person tells you otherwise). Land-line telephones may be less likely to be affected by interference, interruptions, or power outages.

Activities of Daily Living

Your HeartMate system was designed to let you stay active. Be sure to talk to your doctor about your usual activities. Also tell your doctor about any changes in activity level or routine. Because each person is different, your doctor can give you the best advice for your needs. Any time you have questions or worries, call your hospital contact person.

CAUTION !

- Do NOT play contact sports or engage in jumping activities while you have the pump. Contact sports or jumping could cause bleeding or damage your pump.
- The HeartMate II LVAS uses sounds and lights to tell you how the system is working. If you have trouble hearing or seeing, you might need extra help to hear or see the sounds and lights. You might be at higher risk of injury if you have trouble hearing or seeing.
- Always have a back-up Controller, charged spare batteries, battery cables, and compatible battery clips, nearby at all times in case of emergency.
- Do NOT swim or take tub baths while implanted with the pump.
- Do NOT try to fix any of your LVAS equipment yourself. If it needs service, call your hospital contact person.
- Call your doctor or hospital contact person right away if you notice a change in how your pump sounds, feels, or works.

WARNING !

- Do NOT touch television (TV) or computer screens while you have the pump. TV and computer screens have strong static electricity. A strong electric shock can damage electrical parts of the system and cause the pump to stop.
- Do NOT vacuum or engage in activities that may create static electricity. A strong electric shock can damage the electrical parts of the system and make the pump to stop.
- Do not become pregnant while you have the pump. If you are a woman of childbearing age, use birth control if you are sexually active. Blood thinners (which most LVAD patients receive) have been associated with birth defects. In addition, a growing fetus may dislodge the pump, which could cause catastrophic bleeding and death. If you do become pregnant, immediately tell your doctor and hospital contact person.
- Never have an MRI (magnetic resonance imaging) done while you have the pump. An MRI may cause injury or make the pump stop.

Eating

Healthy eating is a good idea for everyone; but it is especially important for people living with a heart pump. A healthy, well-balanced diet can help you recover faster from your surgery. It will give you more energy to be active.

Because of where the pump is located, some patients lose their appetite after implant surgery. This usually goes away over time. If you feel "full" quickly during meals, try eating more (six – eight) smaller meals throughout the day (instead of two or three large meals). Eating more small – but healthy – meals will help you get enough calories and nutrients. Until your appetite comes back, you can also try healthy, high-calorie "shakes." They are found in most food stores and pharmacies.

Your hospital contact person can give you more information and ideas on healthy eating.

Sleeping

You must ALWAYS be attached to the Power Module (PM) during sleep (or when there's a chance you might fall asleep). This is very important because you may not hear the System Controller's alarms if you fall asleep while connected to batteries.

Try to sleep so that you do not pull on or move the percutaneous lead going through your skin. Don't let the lead get tangled in clothing or blankets. To help keep your System Controller from falling or the lead from moving or pulling on the exit site, you can use the HeartMate Stabilization Belt. You can get a Stabilization Belt from your hospital contact person.

Remember these important sleep guidelines:

- Plan to sleep only when connected to the PM.
- Before going to sleep, inspect all electrical connections to make sure they are tight.
- Do NOT sleep on your stomach – most HeartMate patients are more comfortable sleeping on their back.
- Keep a back-up System Controller, charged batteries (already in compatible battery clips), battery cables, and a flashlight near you during sleep.

Intimacy

Sex is an important and normal part of a healthy lifestyle. You should be able to resume sexual activities after recovering from the operation to implant the pump – usually six – eight weeks after surgery. Check with your doctor or hospital contact person.

WARNING!

Do not become pregnant while you have the pump. Use birth control if you are sexually active. Blood thinners (which most LVAD patients receive) have been associated with birth defects. In addition, a growing fetus may dislodge the pump, which could cause catastrophic bleeding and death. If you do become pregnant, immediately tell your doctor and hospital contact person.

Traveling

Being able to travel freely is a big part of everyone's quality of life, whether it's going to the neighborhood store, or traveling out-of-town for a family vacation. But, remember — **with freedom comes responsibility**. If you want to enjoy the freedom of travel, you will need to be able to travel safely.

Talk with your doctor before making any long distance travel plans. He or she will let you know if and when you can travel away from home. Once the doctor approves you for travel, your hospital contact person will help you prepare for traveling safely.

Always follow these important travel guidelines:

- Always keep at least one set of charged batteries, battery cables, and compatible battery clips inside the car and nearby you when using automobile DC power.
- Be sure to bring everything you'll need for battery-powered and electrical-powered operation at your final destination, including:
  - Universal Battery Charger (UBC) and power cord
  - Spare batteries
  - Battery clips
  - Power Module (PM)
  - PM patient cable
  - PM power cord for connecting to AC mains power
  - Backup System Controller
  - Emergency Power Pack (EPP), if prudent or appropriate
- Never leave or store batteries or the EPP in extremely hot or cold places (such as the trunk of your car), or battery life will be shortened.
- Never transport or store batteries in temperatures below -10°C (14°F) or above 40°C (104°F) or they may fail suddenly.
- Never use batteries in temperatures below 0°C (32°F) or above 40°C (104°F) or they may fail suddenly.

- Never transport or store the EPP in temperatures below -15°C (5°F) or above 50°C (122°F) or the EPP may fail suddenly.
- Never use the EPP in temperature below 0°C (32°F) or above 50°C (122°F), or the EPP may fail suddenly.

Note: If traveling internationally, you will need a Thoratec power cord set that is compatible with the local voltage and that meets applicable national plug, rated voltage, rated current, and safety agency marks and specifications for both the PM and UBC. Call your VAD Coordinator or hospital contact person for a Thoratec power cord set, if needed.

Automobile Travel

Automobile airbags deploy with a lot of force. The force could cause damage or bleeding if the airbag hits your abdomen or chest. Therefore, you should avoid riding in the front seat of cars that have airbags (also known as supplemental restraint systems, or "SRS" for short).

Your doctor will decide if you may drive a car or operate heavy machinery while implanted with a heart pump. Some states have laws against letting patients drive if they have a history of syncope or cardiac arrest. Generally, you will need at least six – eight weeks after surgery before you can even be considered for driving privileges.

See "Traveling by Car," found in Section 8.0 of the *HeartMate Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on using automobile DC power to run the HeartMate II LVAS.

Using Automobile DC Power

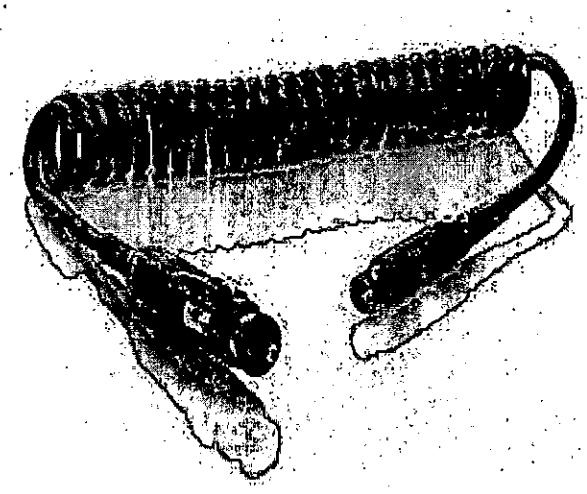
As a convenience, the PM can be plugged into an automobile DC power outlet (e.g. cigarette lighter socket) to power the LVAS while traveling by car. You will need a Thoratec-provided automobile DC power cable (**Figure 42**) to do this. DC power can vary from vehicle to vehicle. If a car's DC power is inadequate to power the PM and LVAS, the PM will alarm or switch to back-up battery power. If this occurs, switch to portable battery power and discontinue the use of DC input power to the PM.

WARNING!

- Your primary source of power during mobile operation (i.e., while not connected to AC mains electrical power) should be the HeartMate batteries. The use of DC power from a car's DC power adapter should be temporary and for convenience only. DC power can vary from vehicle to vehicle. If a car's DC power is inadequate to power the LVAS, the PM will alarm or switch to the internal back-up battery. If this occurs, switch to batteries and discontinue the use of automobile DC power.
- The use of DC power from an automobile power outlet is intended for convenience while traveling by car. DC power from an automobile power outlet is NOT meant to be a primary power source; its use should be temporary only. While traveling by car and using DC power, you should have at least one set of charged HeartMate batteries and cables in close proximity so you can promptly switch to battery power if needed. See the *HeartMate Power Module IFU* (document # 103772) for detailed warnings, precautions, and instructions on using the PM with automobile DC power.

Note: The PM's internal backup battery continues to charge when the PM is connected to a functioning 12 volt DC automobile outlet (just as it does when connected to AC mains power).

Figure 42



Showering

Although you cannot take tub baths while implanted with the pump, you may be allowed to shower after the exit site (where the lead passes through your skin) has healed. Your doctor will tell you if you can shower. Once approved for showering, you must use the HeartMate GoGear shower bag.

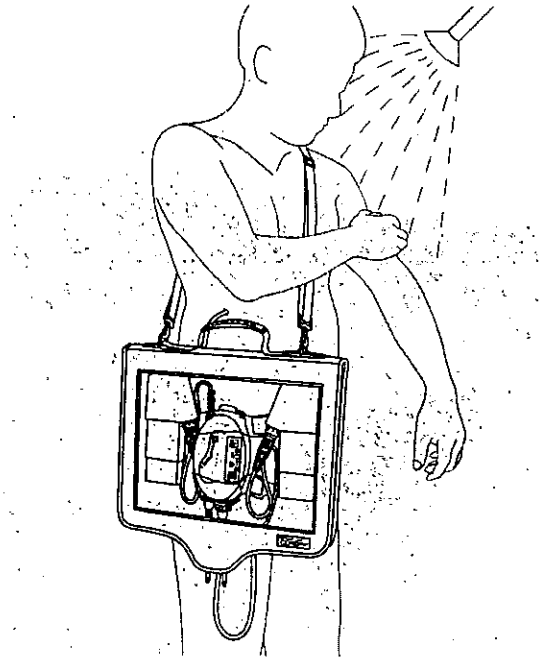
The GoGear shower bag lets you shower safely and comfortably while wearing your HeartMate II system components (batteries, battery clips and System Controller) (**Figure 43**). The shower bag can be used with either batteries or the PM.

The shower bag is water resistant. It protects system components (batteries, battery clips, and System Controller) from water spray and moisture. The exit site also needs to be kept as dry as possible. Although it may feel awkward at first, using the shower bag gets easier with practice.

For detailed warnings, precautions and instructions on using the shower bag, see the *HeartMate GoGear Shower Bag IFU* (document # 104614).

Note: See the HeartMate patient education video for alternatives to tub baths.

Figure 43



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WARNING !

- Do NOT swim or take tub baths while implanted with the pump. You may be able to take showers using the HeartMate GoGear shower bag once the exit site has healed and if your doctor gives you permission.
- **Do NOT take a shower without your doctor's approval**. When you do shower, you must use the HeartMate GoGear shower bag according to instructions.
- NEVER immerse the System Controller, HeartMate batteries, battery clips, or other system component in water or liquid.
- Keep the Power Module (PM) away from water. If the PM has contact with water, shower spray, or wet surfaces, the pump may stop or you may get a serious electrical shock.
- If showering while on PM power, place the PM higher than your exit site to keep water from flowing down the power cable and into the PM.
- The HeartMate GoGear shower bag must dry completely between uses.
- At least once System Controller power lead must be connected to a power source (batteries, PM, or EPP) at all times. Disconnecting both power leads at the same time will cause the pump to stop.

CAUTION !

- Keep the exit site (where the lead passes through your skin) as dry as possible. A dry exit site reduces the risk of infections. Your hospital contact person can recommend strategies for maintaining a dry exit site.
- Try not to pull on or move the percutaneous lead going through your skin. Pulling on or moving the lead could hurt a site that has already healed. This could increase your chances of getting a serious infection.
- Carefully wash your hands every single time before and after changing the exit site bandage(s) or whenever you touch or handle the exit site. Proper hand washing is one of the easiest and best ways to reduce the spread of infection.
- Do not kink or bend the percutaneous lead. Check your lead often to make sure it is free of kinks or sharp bends. A kink or sharp bend in the percutaneous lead may damage the wires inside.

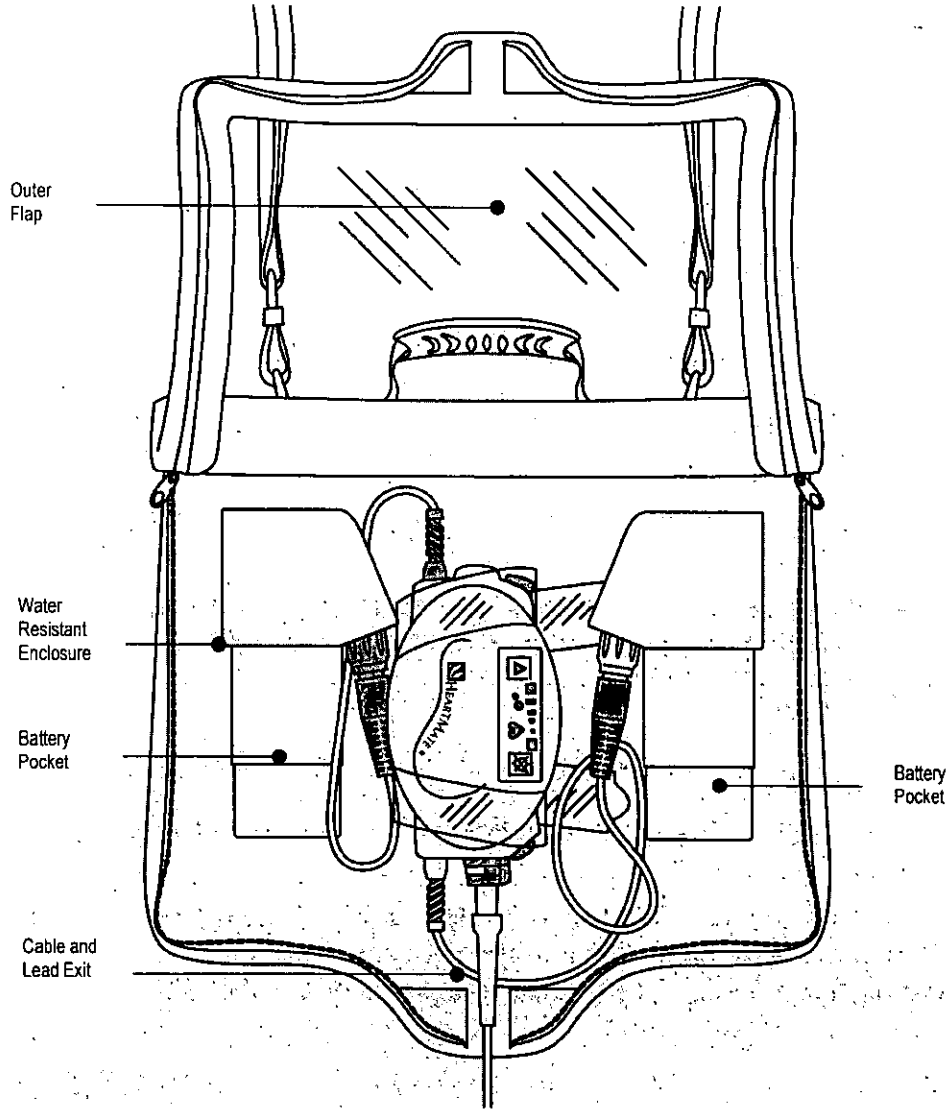
Getting Ready to Shower

1 Unzip and open the shower bag's water resistant enclosure (**Figure 44**).

2 Clip the System Controller into place and secure it using the two Velcro stabilization straps.

3 Put all connectors and cables inside the GoGear shower bag enclosure.

Figure 44



Showering continued

Showering on Battery Power

After following the directions in "Getting Ready to Shower," your System Controller should be properly installed into the shower bag. You are either on PM power and are ready to switch to battery power or you are already on battery power wearing a GoGear holster vest, modular belt, or consolidated bag.

If You are on PM Power and Want to Switch to Batteries for Showering

1. Place two charged batteries and battery clips within easy reach.
2. Insert charged batteries into compatible battery clips.
3. Insert each battery/battery clip, one at a time, into each pocket on either side of the shower bag enclosure.
4. Unscrew the **black** System Controller/ PM power lead connectors. *An alarm will sound.*
5. Put aside the **black** PM power lead connector; then connect the **black** system controller connector to the battery clip connector. *The alarm will stop.*
6. Unscrew the **white** system controller/ PM power lead connectors. *An alarm will sound.*
7. Put aside the **white** PM power lead connector; then connect **white** system controller connector to the battery clip connector. *The alarm will stop.*
8. Keep the PM patient cable connected to, or nearby, the PM until next use.

Note: If leaving the cable connected to the PM when not in use, place the cable where it will not become damaged, dirty, or wet, and so that it will not cause tripping or falling.

Showering continued

Transferring Batteries to the Shower Bag

1 Insert each battery/battery clip, one at a time, into each pocket on either side of the shower bag enclosure.

2 Once you have transferred the batteries/battery clips remove your GoGear wearable accessory (holster vest, modular belt, or consolidated bag).

Showering on PM Power

After following the directions in the "Getting Ready to Shower," your System Controller should be properly installed into the shower bag. You are already on PM power.

1 Place the percutaneous lead and the PM patient cable so that they will both exit through the bottom of the shower bag.

Note: Place the PM higher than your exit site to keep water from flowing down the power cable and into the PM.

Putting on the Shower Bag

After following the directions in either "Showering on Battery Power" or "Showering on PM Power," you are now ready to put on your shower bag.

1 Use the left and right zippers to close and seal the shower bag.

2 Use the shower bag strap to hang the bag either:

- Over your head and shoulder so it's hanging at your side
- Around your neck so it's hanging in front of you.

Note: The strap is adjustable. Adjust the shower bag so it does not pull on the exit site while showering.

3 Keep the exit site as dry as possible.

Note: Proper hand washing and a dry exit site reduces the risk of infections. See *Proper Hand Washing* on page 108 for guidelines. Your hospital contact person can suggest how to keep a dry exit site.

Showering continued

After Showering

1 Use a sterile 4" X 4" gauze bandage to dry the exit site.

2 Apply a sterile dressing to the exit site, using the "sterile" technique taught to you by your hospital contact person (see *Caring for the Exit Site*, on the next page for guidelines).

3 Use a clean, dry towel to dry the GoGear shower bag's exterior and strap.

4 Use the left and right zippers to open the shower bag.

5 Remove all equipment from the shower bag enclosure and return it to your GoGear wearable accessories (holster vest, modular belt, or consolidated bag).

6 Remove the shower bag and allow it to drip dry.

Note: Let the bag dry completely before using it again.

Caring for your Shower Bag

Keeping the GoGear shower bag clean helps it work properly. If your shower bag gets dirty, it can be washed *by hand* using mild detergent and cold water. Once the bag has been washed, hang it to drip dry. Never heat the shower bag to dry it; always let it dry on its own. Make sure the shower bag is completely dry before taking another shower.

Periodically inspect your GoGear shower bag for damage or wear. If you have problems or questions about using the shower bag, your hospital contact person can help you.

Caring for the Exit Site (where the lead passes through your skin)

It is extremely important to keep the exit site (where the percutaneous lead goes through your skin) clean and dry at all times. While you are in the hospital, a nurse will take care of the exit site.

Your nurse will teach you and your family/caregiver(s) "aseptic technique" for changing the bandage, cleaning the site, and checking for signs of infection. Once you leave the hospital, you will be responsible for caring for the exit site.

Keeping the exit site clean and dry helps lower the risk of infection. Here are some tips for keeping your exit site infection free:

- Follow strict "aseptic technique" any time you change the bandage or touch or handle the exit site.
- Wash your hands thoroughly before and after bandage changes. *See hand washing instructions on the following page.*
- Keep the exit site clean and dry.
- Wash the exit site daily using cleanser prescribed by your doctor.
- After washing the exit site, dry the area completely using a sterile 4" X 4" gauze bandage.
- Apply a sterile 4" X 4" bandage to the exit site every time after cleaning it.
- Never put ointments/creams on the site, unless your doctor or nurse says to.
- Try to not pull on or move the lead going through your skin.
- Wear the HeartMate Stabilization Belt or other abdominal binder at all times to keep the lead in place and to prevent pulling on or moving the lead (see *Caring for the Percutaneous Lead,* page 111).

IMPORTANT! Watch the exit site for signs of infection, such as: redness, swelling, drainage, bleeding, or a bad smell. IMMEDIATELY tell your doctor or hospital contact person if there are any signs of infection.

Caring for the Exit Site (where the lead passes through your skin) continued

CAUTION !

- Try to not pull on or move the lead going through your skin. Pulling on or moving the lead could slow healing or hurt a site that has already healed. This could increase your chances of getting a serious infection.
- Do NOT swim or take tub baths while implanted with the pump. You may be able to take showers using the HeartMate Shower Kit once the exit site has healed and if your doctor gives you permission.

Proper Hand Washing

Proper hand washing is one of the easiest and best ways to reduce the spread of infection.

Carefully wash your hands *every single time* before and after changing the exit site bandage(s) or whenever you touch or handle the exit site. Family members or caregivers who help with exit site care must also wash their hands *every single time* before changing the bandages(s) or touching the exit site.

Follow these instructions for washing your hands:

1. Use a paper towel to turn on the faucet(s) for clean, running water.
2. Wet your hands and wrists with the clean, running water.
3. Apply soap to hands. Liquid soap is preferred over bar soap to minimize micro-organism growth.
4. Vigorously rub together all surfaces of the lathered hands for a **minimum of 15 seconds**. Friction helps to remove dirt and microorganisms. Wash around the backs of both hands as well as under rings, around cuticles, and under fingernails.

Proper Hand Washing cont.

5 Rinse hands thoroughly under a stream of clean, running water. Running water carries away dirt and microorganisms. Point fingers down so water and contamination won't drip toward elbows.

6 Dry hands completely with clean, dry paper towel.

7 Use a paper towel to turn off running water.

8 Repeat Steps 1 – 7 every single time before and after dressing changes and touching the percutaneous lead exit site.

Note To keep soap from becoming a breeding ground for micro-organisms, thoroughly clean an empty soap dispenser before refilling with new soap.

Caring for the Percutaneous Lead

While your heart pump should allow you to return to many of your daily activities, it is extremely important to protect your percutaneous lead (often called "perc lead"), especially if you are active. Always keep the perc lead protected and damage-free. Damage to the lead, depending on the degree, may cause the pump to stop.

Remember to follow these guidelines for perc lead care:

- Do not severely bend or kink your percutaneous lead.
- Do not let the lead become twisted.
- If you carry your System Controller in a carrying case, don't "catch" the lead in the zipper.
- Allow for a gentle curve for your percutaneous lead. Do not severely bend the lead multiple times or wrap it tightly.
- Keep your percutaneous lead clean. Wipe off any dirt or grime that may appear. If necessary, use a towel with soap and warm water to gently clean the lead. But, never submerge the lead or other system components in water or liquid.
- Do not pull on or move the lead going through the skin.
- When checking that the percutaneous lead connector is fully inserted into the System Controller socket, gently tug on the *metal end* of the connector. Do NOT pull on the lead.
- Wear the HeartMate Stabilization Belt or another abdominal binder AT ALL TIMES to keep the lead in place and to prevent pulling on or moving the lead.
- Be mindful of where your System Controller is at all times. It is important to protect your controller from falling or from pulling on your lead. Report any drops of the System Controller or snags on the percutaneous lead to your hospital contact person.
- Don't let your percutaneous lead catch or snag on anything that will pull on or move the lead.
- Check the perc lead daily for signs of damage (cuts, holes, tears). If you discover damage, report it immediately to your hospital contact person.

Caring for the Percutaneous Lead continued

- Damage to the electrical wires inside the lead can occur even if you can't see any damage to the outside of the lead. Signs of wire damage may include:
  - Alarms that occur when you move the lead or change your position.
  - High pulsatility index (PI) and/or the need for frequent replacement of the System Controller.
  - Feelings of pump vibrations.
  - Fluid oozing from the external part of the lead.
  - Pump stoppage.

IMPORTANT! If you suspect that you have a damaged percutaneous lead, call your hospital contact person RIGHT AWAY. If damage to the electrical wires inside the lead is confirmed, the HeartMate II pump should be replaced as soon as possible to prevent serious injury or death.

Note Use the NOTES section at the end of this manual to write additional information from your doctor or hospital contact person, if needed.

Pump Replacement

A heart pump, like any piece of mechanical equipment, may need to be replaced. This is especially true if the heart needs long-term help. How long it takes before your pump needs to be replaced depends on several factors. These include how much help your heart needs and how long the pump stays inside you. Your doctor and nurses know this. They will keep track of how your pump is working.

There is no one list of symptoms for when a pump needs to be replaced. But some signs to look for include:

- A return of your heart failure symptoms (like being tired, light headed, or short of breath)
- Alarms happening more often (this also may be your Controller)
- A percutaneous lead that shows damage or wear
- New or strange noises
- New or strange sensations (such as a vibration in your chest)

You have an important role in pump replacement. After all, YOU are living with the pump. So, YOU are one of the best experts in how your pump works, sounds, and feels. If you notice any changes in how you feel, how your pump is working, or how it sounds or feels, call your doctor or hospital contact person right away.

Handling Emergencies

What Is An Emergency?

An "emergency" is any time the heart pump cannot pump enough blood to your body. Examples of emergencies include (but are not limited to):

- Loss of power to the pump
- Broken wires
- Damage to the pump motor or System Controller
- Health changes affecting your heart

If the system is not working right, the System Controller will alarm (see *System Controller Warning Lights and Sounds* on page 18).

Call your doctor right away if you notice a sudden change in how your pump is working (even if there is no alarm). Remember, you know best what is normal for you and your pump.

Note: Consider keeping a land-line (non-portable) telephone in your home for emergency calls, unless your hospital contact person tells you otherwise. Land-line telephones may be less likely to be affected by interference, interruptions, or power outages.

How to Handle an Emergency

It is important to stay **calm** during an emergency! **Most pump problems are easy to solve.**

When the Pump is Running

If a problem arises while the pump is running, you should...

1. Check all lead connections.
2. Reconnect any loose or disconnected leads.
3. Call your hospital contact person if reconnecting the leads does not fix the problem.

Note: See the *Emergency Response Checklist* in the back of this manual for instructions on handling emergencies.

What Is An Emergency? continued

When the Pump has Stopped (Red Heart Alarm)

If the pump stops running, you should. . .

1 Check the connection between the System Controller and the pump and then check the connection between the System Controller and power source (PM, batteries, or EPP).

2 Fix any loose connection(s) then continue with Step 3.

3 Switch to a different power source. If you are on batteries, switch to the PM. If you are on PM power, switch to batteries.

4 Switch to the back-up System Controller (see *Replacing System Controllers* on page 27).

5 If checking connections, switching power sources, or changing System Controllers does not fix the problem, call emergency services right away (dial 911 if available), then call your hospital contact person.

Note: Consider keeping a land-line (non-portable) telephone in your home for emergency calls, unless your hospital contact tells you otherwise. Land-line telephones may be less likely to be affected by interference, interruptions, or power outages.

CAUTION !

Do NOT let the connector ends get dirty or wet.

Safety Testing and Classification

The HeartMate II LVAS has been thoroughly tested and classified by Underwriters Laboratories (UL) to fire, casualty, and electric shock hazard requirements of UL 60601-1:2006 and CAN/CSA-C22.2 No. 601.1-M90: 2002. In addition, the HeartMate II LVAS meets the following safety standards EN 60601-1:1990 and IEC 60601-1: 1998, 2nd Edition, A1:1991, A2:1995.

Table 10 Classification Concerning General Safety

Type	Degree of Protection
Mode of Operation	Continuous
Method of Sterilization	100% EtO for blood pump and all sterile accessories
Type of protection against electrical shock	Class I (grounded) and battery powered
Degree of protection against electric shock	Type CF (Cardio AP, Floating)
Degree of safety of application in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.	Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.
Degree of protection against harmful ingress of water	System Controller - IPX3 Power Module (PM) & Universal Battery Charger (UBC) - IPX0 System Monitor IPX0 (s/n <2000) System Monitor IPX1(s/n >2000)

Medical Electric Equipment
with respect to shock, fire,
mechanical and other specified
hazards only in accordance with
UL 60601-1 and CAN/CSA C22.2
No.601.1-M90 (R1997), CAN/CSA C22.2
No.601.1S1-94, and CAN/CSA C22.2
No.601.1B-98 (National Difference for Canada)

For additional information on testing and classification for the HeartMate II LVAS, please see the *HeartMate II Operating Manual* (document #103884). Your hospital contact person can get a copy for you.

WARNING!

Use of equipment and supplies other than those specified in this manual or sold by Thoratec for replacement parts may result in increased emission or decreased immunity of the HeartMate II LVAS.

WARNING!

The HeartMate II LVAS should not be used adjacent to other equipment or in a stacked configuration with other equipment. The normal operation of the HeartMate II LVAS must be verified when used in these configurations.

Appendices

Before leaving the hospital, you and your family member(s) and/or caregiver(s) will be taught:

- **How to change power sources** (exchanging batteries and switching from batteries to PM or from PM to batteries)
- **What to do in an emergency**

These important instructions are outlined in the following checklists. You and your family member(s)/caregiver(s) need to be able to quickly and safely perform these steps. Doing them incorrectly may make your pump stop. Review these steps until you know how to perform them correctly and without hesitating.

You may be asked to review these steps during follow up visits with your doctor or hospital contact person.

Note: Consider making several copies of the following checklists. Keep copies in your travel case or in your wallet or purse. Put the checklists where you and your family member(s)/caregiver(s) can easily see them and practice the steps. The refrigerator door is an example of a good place to put checklists.

HeartMate II Power Change Checklist

CAUTION: Never disconnect power (batteries, PM, or EPP) from both controller power leads at the same time or the pump will stop.

1 Prepare to change power source (see *Changing from Batteries to PM Power* (page 40) OR *Changing from PM Power to Batteries* (page 37).

2 Remove only one battery from its battery clip or remove the **white** Power Module (PM) power lead from the System Controller.

The power symbol will flash rapidly, the 4 green battery fuel gauge lights will flash, and the alarm will sound once every second.

3 Connect the charged battery or **white** PM power lead to the System Controller.

4 Wait until both the power symbol and the battery fuel gauge lights stop flashing and the alarm stops before going to Step 5.

5 Remove the 2nd battery from its clip or remove the **black** PM power lead from the System Controller.

The power symbol will flash rapidly, the 4 green battery fuel gauge lights will flash, and the alarm will sound once every second.

6 Connect the charged battery or **black** PM power lead to the System Controller.

7 Wait until both the power symbol and the 4 green battery fuel gauge lights stop flashing and the alarm stops before going to Step 8.

8 Check fuel gauge and then continue with appropriate steps to complete the power change:

- See *Exchanging Used Batteries with Charged Batteries*, page 61, or
- See *Changing from Batteries to PM Power*, page 40, or
- See *Changing from PM Power to Batteries*, page 37.

WARNING:

- When changing batteries, never disconnect both batteries at the same time or your pump will stop.
- Your pump will stop if power is removed from both Controller power leads at the same time.
- Your pump will automatically restart only after power is restored.

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HeartMate II LVAS Emergency Response Checklist

Urgent Controller Alarms = **Red Heart**  **with Continuous Audio Tone**

OR

Continuous Audio Tone and no lights on System Controller

WHAT TO DO:

1 CHECK THE CONNECTIONS

Make sure the pump is connected to the System Controller and the power leads are connected to batteries or to the Power Module (PM) cable and PM.

2 If this does not restart the pump, go to step 3.

3 CHANGE THE POWER SOURCE

3a If alarm continues, change power source (switch from PM to fully-charged batteries or from batteries to PM).

3b If this does not restart the pump, go to step 4.

4 CHANGE THE CONTROLLER

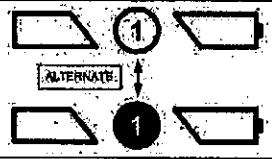
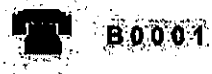
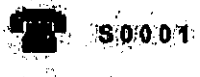
4a Replace System Controller with back-up Controller.

4b If this does not restart the pump, go to step 5.

5 GET ADDITIONAL HELP

If alarm continues, immediately call emergency services (dial 911 if available), then call your hospital contact person.

Description of English Text and Graphic Symbols Appearing on the UBC Display Panel

Meaning	English Mode (on-screen message)	Graphics Mode (on-screen message)
Ready	HeartMate CHARGER	HeartMate CHARGER
Battery Charge Status	X: 	1:  50%
Battery Information (3rd screen)	# = X X: mAh = XXXX	# = X X: mAh = XXXX
Charge Complete	READY X: 	1:  ✓
Request Calibration	CALIBRATE? PRESS X	
Accept Calibration	PROGRESS X: CALIBRATING	1: 
Change Graphics Mode to English	ENGLISH OK ▼	ENGLISH OK ▼
Change Graphics Mode to Symbols	GRAPHICS OK ▼	GRAPHICS OK ▼
Battery Fault	CALL SERVICE	
Charger Fault	CALL SERVICE	
Battery Fault (Button Push)	CALL SERVICE BXXXX	
Charger Fault (Button Push)	CALL SERVICE SXXXX	

Notes